Operating Guidelines for DHBs & Providers

COVID-19 Vaccine Immunisation Programme

Version 15.0

Last Updated 01 July 2021

MINISTRY OF HEALTH
MANATŪ HAUORA

Summary of Changes

Version	Date	Section/ Appendix	Summary of Changes
15.0	01/07/2021	2	Additional abbreviations added
		7	New section 'Vaccinating Border or MIQF Workers'
		9.3 & 9.3.1	Additional recommended vaccination screening question
		9.4.3	Additional step to check the label and confirm expiry time after dilution added (Check vaccine step) Removed expiry date recording instruction under 'Record vaccination information in CIR'
		11	Updated the URL's, SOP Inventory Management PDF and SOP Order Fulfilment PDF
		12	New section about the National Immunisation Booking System (NIBS)
		Appendix B	Added Appendix B: New Facility/Site Setup Form v1.3

Previous revision history can be found in **Appendix C**

Document Approval

Programme Director, COVID-19 Vaccine Immunisation Programme	Joanne Gibbs, National Director of Operations
Signature	Electronic Approval Given
Date	01 July 2021

Contents

1. Purpose

This document provides guidance on establishing and managing a COVID-19 vaccination site, including guidelines for the vaccination workforce. This document is designed to help District Health Boards and providers maintain public safety and ensure consistent and equitable COVID-19 vaccination practices are in place across New Zealand.

This guide will be amended as needed and re-distributed to DHBs and providers. We expect regular iterations based on learnings from the delivery of the COVID-19 vaccine programme. Please ensure you are always using the correct version of the guidelines.

Please note that this document provides operational guidance for the COVID-19 vaccination programme. Clinical guidance is available in the Immunisation Handbook, available at: https://www.health.govt.nz/publication/immunisation-handbook-2020.

See in particular Chapter 2 'Processes for Safe Immunisation' and Chapter 5 'Coronavirus disease (COVID-19)'.

1.1 Focus of current version

The guidance in this document is designed for administering the Pfizer COVID-19 vaccine. This document will be updated should other vaccine types become available.

2. Abbreviations

Abbreviation	Full Name
A&I	Adoption and Improvement
BWTR	Border Worker Testing Register
CARM	Centre for Adverse Reaction Monitoring
CICS	COVID Immunisation Consumer Support
CIR	COVID Immunisation Register
DHB	District Health Board
DNS	Did Not Shown
IMAC	Immunisation Advisory Centre
IPC	Infection Prevention and Control
MIQF	Managed Isolation and Quarantine Facility
MoH	Ministry of Health
NHI number	National Health Index number
NIBS	National Immunisation Booking System (Book My Vaccine)
ULT	Ultra-Low Temperature (-90°C to -60°C)

3. Key Contacts

A 'Where to get help' poster is available in the MoH dropbox for you to share with your sites. This includes details of the CIR helpdesk number and email address and the MoH Logistics team's contact number and email address.

Issue Type	When to Contact	Contact Details	Hours of Operation
IT hardware or non-COVID Immunisation Register (CIR) software issues	Logging technology hardware or software issues that *aren't* CIR-related	Contact your local IT ServiceDesk	Ensure after-hours support is available for sites operating outside business hours
COVID Immunisation Register Issues	For help on using CIR Logging-in issues, password resets, or after hours help,	Refer to the 'Where to get help' poster	8am-6pm, weekdays & weekend
Vaccine or Consumables Supply Issues	To raise an issue with supplies	Refer to the 'Where to get help' poster	Email: 9am-5pm, weekdays Phone: 8am-8pm, weekdays & weekends
Clinical Vaccine Queries	To receive clinical advice on the vaccine or vaccination process	0800 IMMUNE (466 863), option 1 (Health professionals) and then option 2 (COVID vaccinator support)	Available during site operating hours
Order Vaccination Collateral	To request additional pamphlets or other collateral	Your DHB Communications Manager	
Privacy Incident or Concern	If you identify a known or suspected privacy breach	Refer to the 'Where to get help' poster	9am-5pm weekdays
Adverse Event Following Immunisation	Reporting an adverse reaction to the vaccine	https://report.vaccine.covid19.govt.nz (03) 479 7247 carmnz@otago.ac.nz	
Interwaste Vial Disposal Bin Requests/Collection	To arrange first delivery of vial disposal bin and collection of full bins	0800 102 131	8am-5pm, weekdays

4. Roles and Responsibilities

Activity	Ministry of Health	DHBs & Providers	Group 1 Employers	IMAC	CARM	Distribution Provider
Purchasing	• Purchase vaccine from Pfizer • Purchase consumables including PPE	N/A	N/A	N/A	N/A	N/A
Distribution	• Arrange distribution of vaccine and consumables to vaccination sites/DHB facilities	• If needed, arrange secure distribution from DHB facility to vaccination site	N/A	N/A	N/A	• Thaw and repack vaccine into sub-batches as needed • Distribute vaccine & consumables
Inventory Management	• Coordinate allocation schedule • Order vaccine & consumables for DHBs	• Plan vaccine demand to minimise wastage • Report stock on hand, stock movement & exceptions • Ensure vaccine handling & storage requirements are met	N/A	N/A	N/A	• Perform QA checks on receipt of vaccine from Pfizer • Ensure secure storage of vaccine prior to distribution
Workforce & Training	• Provide guidance on workforce model and training requirements • Provide access to CIR for vaccinators & admin staff • Provide CIR support/factsheets	• Hire and roster vaccinators and required site support staff • Provide info to MoH and IMAC for user on-boarding & provision of training • Ensure staff are appropriately trained	N/A	• Provide vaccine preparation & delivery training • Provide CIR training	N/A	N/A
Site Operations	• Provide guidance on preparing and running vaccination sites • Disseminate process improvements (e.g. via updated Operating Guidelines)	• Prepare & run vaccination sites, incl. providing IT equipment and disposing waste • Work with Group 1 employers to schedule vaccinations of staff • Schedule appts for household contacts • Engage with Māori & Pacific Island partners around vaccination of household contacts	• Liaise with DHBs if vaccination site is on employer premises to ensure site is set-up and secured	• Provide clinical support to vaccinators as needed	N/A	N/A
Post-Event	• Monitoring adverse event data	• Dispose of expired, empty or broken vaccine vials and used consumables • Pack down site as needed	• Where vaccination on employer premises, support pack down of site • Provide employee support	N/A	• Receive and investigate adverse event reports	N/A
Comms & Engagement	• Coordinate national vaccine engagement campaign • Provide key messages to DHBs to share with Group 1 employers • Engage with household contacts • Provide collateral files to DHBs/providers & distribute site banners/cards • Manage adverse event comms	• Engage with Group 1 employers re: sites & schedule • Print and circulate collateral to vaccination sites as required • Engage with household contacts	• Engage with employees re: vaccination plan	N/A	N/A	• Include 'Instructions for the Pfizer Vaccine - Preparation and Administration' info sheet in vaccine shipments
Reporting	• Produce programme and operational reporting	• Complete weekly stock on hand and stock movements reporting • Report exceptions to plan, as they occur	N/A	• Provide data on vaccinators trained to date	• Provide adverse event data to MedSafe	• Provide stock on hand and orders out reporting to MoH

5. Preparing a Vaccination Site

5.1 Equitable Access

You should ensure that your vaccination sites are accessible to all members of your community and ensure equitable opportunity for Māori and Pacific people, other ethnic communities, and disabled people. You should take reasonable steps to improve access and reduce potential inequalities. This may include:

- Providing access to translation and interpretation services to support the consent and immunisation processes. For more information on interpreter services see https://www.healthnavigator.org.nz/languages/i/interpreter-services/
- Ensuring key written material and any signage is in easy to read formats.
- Providing supporting literature available in a range of languages and resources/support for those who have low health literacy. This may include access to New Zealand Sign Language (NZSL) if needed. **Note:** MoH has prepared translations of COVID-19 vaccine information (see section 'Ordering Site Collateral' below).
- Considering how your service delivery model caters for support people that consumers may bring to the vaccination event (e.g. friends, whānau or carers).
- Encouraging site staff to greet consumers in Te Reo or the language the consumer uses where possible

5.1.1 Te Tiriti and Māori

- Actively incorporating Te Tiriti O Waitangi considerations, including:
    - making sure Māori are not disadvantaged
    - mitigating the impact to Māori as a result of COVID-19
    - establishing and maintaining effective partnerships with Māori stakeholders including iwi, hapu and whānau
    - seeking Māori specific advice from the outset
    - resourcing and investing where it is required the most
- Starting and ending the day with a karakia

5.1.2 Māori and Pacific Peoples

- Ensuring your site workforce reflects the demographic make-up of the likely consumer group or local area.
- Considering which site locations can best meet the community's needs in terms of both ease of access and comfort or familiarity with the location (e.g. marae, churches).
- Where drive-in sites are planned, ensuring consumers can either attend this site if they do not have a car or have access to a non-drive-in site.
- Building early and regular engagement with Māori and Pacific partners into your service delivery model to design for the community's needs.

5.1.3 Disability

- Ensuring access for disabled people, including venue accessibility and accessible information. For more information on venue accessibility, see the Ministry of Health website.
- Designing site support processes to support individual with visual or hearing impairments, e.g. providing a card to ask individuals to advise site staff if they have a hearing impairment to ensure their needs can be met during the vaccination or any follow up interactions.

- For Deaf or hard of hearing community members, you may need to arrange a New Zealand Sign Language (NZSL) Interpreter. Information on working with NZSL Interpreters can be found here https://www.odi.govt.nz/nzsl/tools-and-resources/.
- Ensuring staff are educated in disability equity issues and know how to employ a rights-based approach. A 30-minute eLearn is available through the Ministry of Health LearnOnline website (https://learnonline.health.nz/login/index.php - Disability Equity eLearning).
- Enabling people to access appropriate support and accommodations that they might need for a successful vaccination i.e. are there any measures as a site or team that you can implement to support mobility constraints, or accommodate individuals, families and whānau if someone has an anxiety or phobia, or may need a quiet and low stimulation environment.
- Supported decision-making is an important process for people who might need support to make decisions. This may be needed because of a person's communication needs, learning disability, acquired brain injury, neurodiverse needs, mental health issues or due to other cognitive and physical conditions. Supported decision-making is a way for people to make their own decisions based on their will and preferences, so they have control of their life. It ensures the person who needs support is at the centre of all decisions that concern them. Training on supported decision making will be available mid-June 2021.

5.2 Site Access and Traffic Management

Waka Kotahi NZ Transport Agency has provided the following advice to support site location and traffic management planning.

In addition to the considerations below, you may also find the Waka Kotahi Journey Planner useful for assessing how people will access your sites. Similarly, Regional Council websites also contain valuable information about local public transport provision.

5.2.1 Access considerations

When choosing your location, consider how easily people might be able to access the site. For example, you should consider the following questions:

- How will people with mobility issues access your site?
- Is there a public transport stop within 500m of your site?
- Are there multiple routes and/or multiple modes of public transport within 500m?
- Is there cycling or walking access?
- Is there adequate parking available for people to reach your site by private vehicle?
- Are there opportunities to locate the site in place that will reduce the number of additional trips people need to make?
- Will additional signage be required to direct people to the location of the centre?
- How would a change in alert levels affect the site?
- How will people who live in areas that are not serviced by public transport reach your site?

5.2.2 Traffic management considerations

As the numbers of people receiving vaccines increase, consider how this will impact the traffic network. Bear in mind the following:

- How will the increase in road users impact vehicle congestion?
- How many different routes can people use to access the site?
- What are the current levels of congestion at different times of the day?
- Is the site close to major arterial roads or state highways, which may give greater access?

- Does your site location provide easy access to public transport to mitigate impacts on road congestion?
- Are there any planned roadworks, road closures, or event that may impact on access?
- Will any potential queues to your facility affect access to key services such as emergency services, health centres or schools?
- Could you provide multiple small sites instead of a few major locations servicing large numbers of people to better disperse demand across the transport system?
- Can your booking system be used to manage demand on the facility and take into account peak traffic times?

5.3 Clinical Leadership

Every multi-vaccinator immunisation site should have a named lead clinician. The onsite lead clinician should be an appropriately experienced clinician who is able to lead the vaccination team, manage adverse events, and provide onsite clinical advice.

5.4 Quality and Safety

There is an expectation that each DHB region has a quality and safety oversight of the vaccination programme rollout through their existing quality and safety and/or clinical governance mechanisms. For clarity, this includes adverse event, complaints and incident management (Note: In this context, 'adverse event' does not refer to an adverse reaction following immunisation).

5.5 Infection Prevention and Control (IPC)

The key IPC principles to consider and the precautions for safely delivering COVID-19 vaccines are described below. These principles and recommendations have been derived from the World Health Organisation (WHO) guidance.[1]

This guidance is intended for policy makers, immunisation programmes and IPC leads for vaccination delivery venues. This section covers the IPC measures required to support all vaccination activities, and as such, some aspects may also be covered in other sections of the operating guidelines.

5.5.1 Key IPC principles for COVID-19 vaccine deployment

Standard precautions to be applied during any vaccination activity are also valid for COVID-19 vaccine delivery, considering that the population to be vaccinated consists of individuals **not** presenting signs and symptoms of infection.

However, additional IPC precautions may be necessary in the context of the COVID-19 pandemic to reduce the risk of transmission (e.g. PPE usage in line with IPC guidelines per the Alert Level).

It is critical to provide health workers with specific training and the public with targeted information regarding IPC measures for safe COVID-19 vaccine delivery.

A clean, hygienic and well-ventilated environment, appropriate waste management and adequate spaces that facilitate best IPC practices (e.g. physical distancing) are necessary for COVID-19 vaccination activities.

National guidance and protocols for IPC measures should be consulted and adhered to.

5.5.2 Preparation and planning phase

Appoint a facility IPC lead for the planning, deployment and monitoring of the vaccination activities.

Identify an adequate number of vaccinators to ensure there is sufficient staff and time to support correct implementation of the IPC practices required to safely administer the vaccine.

[1] Aide-Memoire Infection prevention and control (IPC) principles and procedures for COVID-19 vaccination activities, 15 January 2021. *https://apps.who.int/iris/handle/10665/338715*

Identify trained staff to deliver IPC training to those involved in vaccination activities (including managers, logistical support vaccinators, cleaners and health workers dedicated to screening) and to provide information for people to be vaccinated.

Identify health workers for the supervision of vaccination activities and define a monitoring and evaluation process of IPC practices, including providing feedback to vaccinators and other staff as required.

MoH recommends you create vaccination site specific COVID Tracer App QR code posters. You can create QR code posters using the current self-service webform. More information about QR code posters is available on the Ministry of Health website.

5.5.2.1 Local IPC Guidance

Develop local IPC guidance and standard operating procedures for COVID-19 vaccination, outlining the following:

- screening policies for COVID-19 signs and symptoms of staff and individuals arriving for vaccination with clear exclusion criteria;
- key IPC measures to be taken by anyone in the vaccination area or clinic
- key IPC measures for safely administering COVID-19 vaccines;
- cleaning and disinfection of the environment;
- appropriate waste management taking in consideration the increase of waste associated with COVID-19 vaccination activities, and where possible include environmentally-friendly approaches to manage both general and medical waste at point of use, segregation, disposal and collection;
- visual reminders emphasizing hand hygiene, safe injection practices, respiratory hygiene, and other IPC measures;
- training materials for relevant staff and educational and informational materials for the public.

5.5.2.2 Environmental considerations and engineering controls at the vaccination venue

Assess the layout of the building or area identified for vaccination delivery and ensure that the following features are in place to support appropriate IPC implementation:

- clearly marked one-way foot traffic flow with clear entry and exit areas through the vaccination clinic; these should be separated when the vaccination area or clinic is located in a health care facility;
- adequate screening area (ideally, private spaces) at the entry where people are assessed, including questioning for signs and symptoms of COVID-19 and other criteria for inclusion;
- sufficient space to allow at least 1 metre physical distance between all individuals including between health workers at all stations (at the entrance, at the screening stages, while waiting to be vaccinated and during the observation period post-vaccination) and between staff;
- adequate ventilation (mechanical, natural or hybrid) of all areas, including the screening, waiting, post-vaccination observation, and vaccination areas; if a mechanical ventilation system is operating in these areas, the ventilation rate should be 6 air changes per hour or according to national or local requirements for healthcare facilities;
- medically equipped post-vaccination observation area for dealing with possible vaccine adverse reactions;
- adequate number of hand hygiene stations in strategic areas to support appropriate hand hygiene for the public and staff (i.e., at the entrance and exit areas, in the waiting areas, and in each vaccination station);
- laminated signage/posters to include reminders about:
    - reporting COVID-19 signs and symptoms;
    - hand and respiratory hygiene;
    - physical distancing (e.g. floor markings, seating arrangements, tapes, ropes, and cones);

- adequate space for vaccine storage and preparation (e.g. clean and hygienic environment, adequate ventilation and equipment to adhere to specific COVID-19 vaccine cold chain requirements);
- vaccination stations a least 1 metre apart (ideally with installation of physical barriers between vaccination stations);
- adequate 'cleanability' of screening areas, vaccination stations, waiting areas (e.g. removal of items that cannot be readily decontaminated and minimizing clutter to aid effective cleaning);
- appropriate waste management system including safe disposal of waste (such as vials and masks) and sharps at each vaccination station (see also 'Disposal of Consumables, Vaccine and Vaccine Packaging' section below).

5.5.2.3 IPC supplies

Ensure that there is a continuous and sufficient supply of the following:

- Personal protective equipment (PPE) including eye protection, long-sleeve fluid resistant gowns and gloves, in case it is required for vaccination team's protection when dealing with a vaccine adverse event, to prevent exposure to non-intact skin to blood and body fluids or if a suspected case of COVID-19 is identified during the screening process.
- Other supplies include; alcohol-based hand sanitisers, thermo-scans for temperature screening, tissues; waste bins and bin liners, sharp disposal bins, cleaning and disinfection products, visual reminders and signage and physical barriers to aid spatial separation.

Identify a suitable area for storage of supplies.

5.5.3 Operational phase

Use a daily checklist to monitor and ensure that the IPC and other safety measures are adhered to.

Consider a daily 'huddle' to enhance teamwork and to highlight any IPC issues.

Screen all staff for signs and symptoms of COVID-19 at the start of each shift.

Screen all people arriving for vaccination for COVID signs and symptoms, especially those people who meet the New Zealand Government 'higher index of suspicion' (HIS) criteria.

Ensure that the scheduling of vaccination appointments avoids over-crowding and allows for physical distancing and other IPC measures. Also, limit the number of accompanying people to only those who need assistance, whether physical or psychosocial.

5.5.3.1 Key IPC measures to be implemented

Hand hygiene:

- Vaccination team members to wash their hands with soap and water and dry thoroughly or use hand sanitiser at the start of the shift.
- Facilitate hand hygiene by people attending for vaccination
- Vaccinators should perform hand hygiene before putting on and removing PPE, before preparing the vaccine and between each vaccine administration, preferably using alcohol-based hand sanitisers.
- Gloves are not required and, if used, do not replace the need for hand hygiene between each vaccine administration and for other indications. The use of alcohol hand sanitisers on gloves is strongly discouraged.

PPE:

- Select PPE based on risk assessment as part of Standard Precautions
- In the context of COVID-19 pandemic, vaccinators should wear PPE appropriate to the public health risk and current COVID-19 Alert Level settings

Injection safety:

- Sterile, single use syringes and needles should be used. These should only be removed from their packaging immediately before use.
- Perform hand hygiene before preparing vaccine for delivery
- Prevent contamination of the vials by wiping the access diaphragm (septum) with 70% alcohol (isopropyl alcohol or ethanol) on a swab or cotton wool ball before piercing the vial and allow to air dry. If the top of the vial is accidentally touched during drawing up it must be re-wiped (repeating this step).
- Adhere to IMAC guidance for the drawing up of vaccine and skin preparation at the site of injection
- Discard used syringes and needles as a single unit into a sharps container immediately after administering the vaccine

5.5.3.2 Environmental cleaning and disinfection, waste management

Prepare each injection in a clean, designated area.

Perform regular environmental cleaning and disinfection of areas and sites where vaccination occurs at least twice daily with special attention to high touch surfaces. Use recommended detergent and disinfectant products.

Seal and remove sharp containers when filled and stored in a secure area for transportation and final disposal

Manage sharps waste as per NZS 4304: 2002: Management of Healthcare Waste.

5.5.3.3 MIQF requirements

If the vaccination site is located within a Managed Isolation and Quarantine Facility (MIQF). In that instance, staff must abide by the IPC guidance set out for workers in MIQF in the MIQF Operations Framework.

5.6 Ordering Interwaste Vial Disposal Bin

As part of your site preparations, please contact Interwaste to arrange the delivery of an Interwaste vial disposal bin (see 'Disposal of Consumables, Vaccine and Vaccine Packaging' section below).

Contact Interwaste on 0800 102 131 as soon as your site is confirmed. You should provide at least 48 hours' notice before you need the container to arrive. Interwaste will collect the relevant details such as the site manager's name and contact details, the delivery date for the first container, and the site delivery address information.

5.7 Incident Management & First Aid

The site team should be trained and prepared to respond to three possible medical emergencies associated with COVID-19 vaccination: fainting, hyperventilation and anaphylaxis. The appropriate medication and equipment must be on site to manage these incidents.

Refer to section 2.3 of the Immunisation Handbook for guidance on emergency equipment required to manage post-vaccination medical emergencies.

5.8 Occupational Health Requirements

Ensure you have appropriate occupational health requirements in place for your site team, including an accessible needlestick injury protocol. Staff must understand what to do and who to contact if they experience a needlestick injury.

5.9 Business Continuity

Ensure you have a business continuity plan in place for your sites, e.g. to manage power failures.

Hard-copies of the following forms should be available on site in the event CIR is unavailable:

- Consent form (required consumer data fields that will need to be added to CIR are included on the back of this form)
- COVID-19 Vaccine Adverse Event Report. This is the form used to submit adverse event information to the Centre for Adverse Event Monitoring (CARM). If CIR is unavailable, you may use this form to capture relevant information, noting that on-site adverse events must be reported in CIR as soon as practicable (as distinct from submitting the form to CARM).

See 'Ordering Site Collateral' section below for information on obtaining these forms.

Any hard copy forms must be entered into CIR by close of business on the following day. Make sure any printed copies of information are locked away when not in use.

5.10 Protecting Security and Privacy

The vaccination process will require personal, identifying information to be collected. In the health sector, NHIs are considered identifiable information as well as standard identifiers such as name, address and date of birth.

Health information can be sensitive so it is important that it is protected and treated with respect.

- All medical records (e.g. written consent forms) at vaccination sites will need to be securely stored out of the sight of patients (e.g. a drawer) and it is preferable that this drawer is in the constant presence of an authorised person (e.g. administrator, security guard or vaccinator) or alternatively it can be locked.
- At the conclusion of the vaccination event the personal information documentation needs to be taken directly (no transit points) by an authorised person (e.g. administrator, security guard or vaccinator) to the site where the record will be held.

In addition to ensuring the security of health records as per above, you should also consider the following security and privacy factors:

- Tell people why you're collecting their information and what it will be used for (e.g. that it will not be used for immigration or law-enforcement purposes)
- Think about who can see your computer screen if you're looking at personal information
- Keep your password and log-in details confidential
- If you spot something going wrong, let your DHB or provider privacy officer know or contact the MoH Privacy team as soon as possible
- Dispose of unnecessary duplicate information securely
- Be mindful about people overhearing confidential conversations in public places
- Use secure methods when transferring information outside of the core vaccine systems, e.g. when emailing or using USBs or online cloud storage password protect the data

5.11 Vaccine Security

To ensure the security of the vaccine, please ensure the following minimum standards are met:

- The vaccines must be stored in a work area that has the constant presence of an authorised person (e.g. administrator, security guard or vaccinator) during hours of operation.
- If the vaccine is to be stored overnight at the vaccination site, then the building should be in a controlled-access environment (e.g. Maritime Port or Managed Isolation and Quarantine Facility (MIQF)).
- If the building is not in a controlled-access environment (e.g. Community Hall), then the building should be able to be secured and have a monitored alarm.
- In the event the vaccines are stored at a vaccination site that does not have controlled access and is not a building (e.g. a tent) then an overnight onsite security guard should be present.

5.12 Site Physical Security

To ensure the safety of patients and staff all vaccination sites should have a security presence to control access to the site and be available to support in the event of attempted unauthorised access (e.g. public attempting to obtain a vaccination) or protest action.

Vaccinators will not require security to travel to the immunisation sites but secure parking and how vaccinators gain access to the site should be considered (e.g. separate access from the general public).

5.12.1 Sharing Information on the Vaccine

The Medicines Regulations (1984) requires that written information is provided in the form of a data sheet which is available online at https://www.medsafe.govt.nz/medicines/infosearch.asp; the COVID-19 vaccine data sheet can be found by searching 'COVID-19'. There is no legal requirement for any hard copy data sheets or medicine package inserts to be provided on site.

5.13 Site Security Assessment

All vaccination sites will need to be able to ensure the following:

- Staff safety
- Patient safety
- Security of the vaccine (storage facilities, in-transit, at vaccination sites)
- Security of information – particularly paper-based information i.e. spreadsheets
- Confidence that contingency plans exist to deal with a 'disturbance'/potential protest event at a vaccination site.

A documented risk assessment should be conducted for every individual vaccination site. This should include, but is not limited to, the following considerations:

- How will staff travel to the vaccination location?
- Will secure parking be provided for vaccinators and administrators?
- How is access to the site controlled?
- How is the vaccine transported to and from the location?
- How is the vaccine securely stored at the vaccination location?
- How are consumables including needles securely stored at the vaccination location?
- How is hard copy information (if any) securely stored at the vaccination site?
- How will staff act if there is any disruption e.g. protest activity or if persons other than border workers or their household contacts turn up for vaccination?

5.14 IT Equipment

You'll need to cater for the following IT requirements at vaccination sites to ensure staff can access the COVID-19 Immunisation Register (CIR):

Requirement	Details
Network	A secure network (Wi-Fi, hard wired, or 4G) with connectivity to the device running CIR and to the user's mobile phone or computer. Wi-Fi specifications: • Coverage ranging to reception, vaccination and waiting areas within the site • Highly available network (e.g. Fibre & 4G backup)

Internet Browser	**Chrome** is the recommended internet browser; however, other browsers will support CIR. Internet Explorer is **not** supported (use Microsoft Edge if needed). For further information see: https://help.salesforce.com/articleView?id=sf.getstart_browsers_sfx.htm&type=5
Computer or Tablet Device	Any laptop from the last 5 years should be compatible with CIR so long as it has browser access. For further information see: https://help.salesforce.com/articleView?id=sf.getstart_browser_recommendations.htm&type=5
Mobile Phone	CIR users require an **iOS or Android** mobile phone to download the Salesforce Authenticator application. This can be downloaded from the App Store on iOS and the Play Store on Android. You can scan the QR code on the right to locate the Salesforce Authenticator app in the relevant App Store.

Prior to starting vaccination, make sure you have tested all IT equipment and that all staff have received the necessary training to use the devices and CIR.

Make sure you advise each site team where they can access additional IT support (i.e. for non-CIR issues such as hardware issues), including after-hours support if your vaccination site is operating outside standard business hours.

5.15 COVID-19 Immunisation Register (CIR)

The COVID-19 Immunisation Register (CIR) is a browser-based system where you'll record all vaccination details. CIR using email address, phone number and 6 identifiers to match consumer records with NHI records.

Once you've joined the COVID Vaccination Immunisation Programme, you'll need to request access to CIR for your vaccinators and administrators following the process outlined below.

5.15.1 Access to Training, CIR Classroom, and CIR

Staff need to complete the Immunisation Advisory Centre (IMAC) training by registering at lms.immune.org.nz. Users will complete CIR and/or Pfizer eLearning modules. CIR users will also be invited to attend a drop-in session where they can ask any CIR questions they may have.

To support their training, CIR users will be granted access to CIR Classroom where they can practice using the system. To gain access to CIR Classroom, the DHB or provider workforce lead must send a list of all staff requiring CIR Classroom access to MoH.

Once staff have completed required training, the DHB or provider workforce lead must confirm to MoH that the staff member is now 'approved' and MoH will then give them access to the live CIR environment. **Note:** You must supply an organisation email address for all CIR users to obtain access to the live CIR environment.

5.15.2 New User Onboarding Support

For any questions or support on new user onboarding, please contact your regional account manager.

5.15.3 CIR Support

If the site team requires CIR support, they should contact their super user in the first instance or join a drop-in session before contacting the CIR ServiceDesk.

CIR eLearning modules and Quick Step Guides are available to all staff (see 'Staff Training and Reference Materials' section below).

5.16 Ordering Site Collateral

MoH has prepared the following collateral to support the vaccination programme. Files will be shared with DHB Comms Managers via an existing All of Government (AoG) Dropbox or via a MoH weblink and these can then be printed and supplied to sites.

Translations are now available in the following languages on the MoH website, with additional languages to be added:

- Māori
- Hindi
- Samoan
- Simplified Chinese
- Tongan
- Cook Island Māori
- Fijian
- Tagalog
- Niuean
- Tokelauan

IMAC has also prepared a consent video which can be displayed on sites in site reception areas if desired. This video is available on the IMAC website.

Note that you may also arrange for a translator to be available on site to assist consumers who speak languages other than English, including New Zealand Sign Language. See the 'Equitable Access' section above for more information about translators.

Purpose	Collateral	How to Order
To share with consumers on site or before attending the vaccination site	COVID-19 Vaccine Information & Consent Pack, which includes: • Getting your COVID-19 Vaccine: What to Expect • Consent form • After your immunisation • Privacy statement	Contact your DHB Comms Manager
	COVID-19 Vaccine FAQs	Available on MoH website
To provide after the consumer has been vaccinated	Vaccine record and appointment card	MoH will arrange distribution of physical cards to sites.
To collect household contact information on site *(only to be used if consumers cannot access the online form or 0800 number)*	Household contacts of Border Workers form	Contact your DHB Comms Manager
For use if CIR is unavailable	Consent form (which includes fields to capture required consumer data)	Contact your DHB Comms Manager
	COVID-19 Vaccine Adverse Event Report	Available on the Centre for Adverse Event Monitoring (CARM) website: https://report.vaccine.covid19.govt.nz
	Vaccine Error Reporting Form	Contact your DHB Comms Manager

Purpose	Collateral	How to Order
To be displayed on site	Pull-up banners for site (2 designs: 'Vaccinations here' and 'Protecting our people')	MoH will arrange distribution of banners to sites.
	Teardrop flag for outside site	MoH will arrange distribution of flags to sites.
	COVID-19 vaccine posters (A3/A4 size)	Contact your DHB Comms Manager
	Large vaccination site poster (A0 size)	MoH will arrange distribution of these large posters to sites.
For vaccinators and staff on site	Instructions for the Pfizer Vaccine - Preparation and Administration	This will be included in vaccine shipments and are available on the IMAC website.
	'Where to get help' poster	Contact your DHB Comms Manager Also available via the CIR homepage

5.17 Site Readiness Checklist

Complete the site readiness checklist included in **Appendix A** to assess whether the vaccination site is ready to commence vaccinations.

Once complete, site checklists must be signed by your DHB or provider Chief Executive or their delegate to approve the site is ready and the checklist then submitted to either your regional account manager or the MoH Logistics team. If you are a primary care provider, you may be asked to submit your site checklist to your DHB rather than to MoH directly.

You must also submit the 'New Facility/ Site Set Up Form (v1.3)' form five days prior to the site commencing vaccinations (**Appendix B**). This information is used to set up your facility or site in CIR and ensure deliveries are made to the correct address so please ensure information on this form is accurate. Your regional liaison will provide this form to you.

5.17.1 Completing a dry run

MoH recommends you complete a site trial or dry run before beginning vaccinations on site to ensure staff are familiar with their roles and consumer flow can be tested. MoH has prepared a pack to help you run your dry run; contact your MoH regional liaison to get a copy of the latest pack.

6. Preparing the Vaccination Site Workforce

6.1 Vaccinating Your Workforce

Prior to commencing vaccinations, MoH recommends you offer all vaccination site staff an opportunity to receive a COVID-19 vaccination. This includes all staff who have contacts with consumers, from health professionals to receptionists and security staff.

6.2 On-Site Functions

MoH has identified the following functions for the site team. Note that someone with a clinical role (e.g. a vaccinator) may perform non-clinical functions, particularly in smaller sites.

This table is not intended to be a prescriptive list of all functions on site and expectations for different roles; rather, it outlines what likely functions will be required to aid in your workforce planning.

Non-Clinical Functions	Clinical Functions
• Greeting consumers and answering questions • Identifying accommodations and additional support that consumers may require, i.e. mobility support, low sensory / quiet spaces, interpreters (including New Zealand Sign Language interpreters) • Confirming consumer identity • Entering consumer information into CIR • Providing COVID-19 factsheets and FAQs • Directing the consumer to the Privacy Statement • Recording the vaccine details in CIR • Advising the consumer when they can depart the observation area • Providing the vaccination receipt card • Capturing household contact information from Border and MIQF workers where this information has not already been provided • Completing or arranging daily cleaning of the site • Arranging collecting of medical waste • Decommissioning the site when it is no longer needed • Providing reporting back to MoH or DHB or provider leads as needed	• Preparing the vaccination dose • Obtaining consent to receive the vaccination • Asking health questions prior to administering the vaccine • Vaccinating the consumer • Monitoring consumers in an observation area for any adverse events • Attending to adverse events and recording them Staff performing clinical functions must be appropriately trained to administer the Pfizer vaccine by the Immunisation Advisory Centre (IMAC).

6.3 Workforce Modelling

The size of the vaccination site and volume of vaccinations expected to be delivered on site will determine the size of the workforce required. The following tables outline staffing models for you to consider as you plan your vaccination workforce.

Note that the modelling below is only recommended and you should tailor your resourcing based on your expected site volumes, your service delivery model and your understanding of the needs of the consumers (for example, if the cohort being vaccinated is expected to have low health literacy or low English skills, they may need more support throughout the process which may affect timing and resourcing).

Please refer to Appendix 4 in the *Immunisation Handbook* for further guidance on criteria for authorised vaccinators and minimum staff and equipment requirements for the provision of vaccination services.

Waiting Room		Immunisation Event	After the Event
Activity	Consumer checked in; may watch a consent video in the waiting room (~10mins).	Consumer and vaccinator will have clinical conversation about the vaccination and consumer will provide consent. Immunisation occurs. Administrator will enter details into CIR as the vaccinator performs the vaccination	Consumers must remain onsite for 20 mins after the event for monitoring.
Staffing	1 x Administrator	1 x Administrator 1 x Vaccinator	1 x Registered Health Professional minimum specifications in Appendix 4.2 of the *Immunisation Handbook*. 1 x support person with CPR training

Based on the activities and staffing numbers above, MoH recommends the following site staffing numbers:

If 20 vaccinations per day	If 120 vaccinations per day	If 360 vaccinations per day
• 2 vaccinators working at the site who will undertake all roles	• 1 Admin in waiting room • 3 Vaccinators* • 3 Admin support • 1 Vaccinator drawing up • 1 Registered Health Professional and 1 Support person monitoring during observative period	• 1 Admin in waiting room • 9 Vaccinators* • 9 Admin support • 3 Vaccinators drawing up • 2 Registered Health Professionals and 1 Support person monitoring during observative period

Notes:

***Note 1:** If COVID-19 Vaccinators are utilised there must be 1 dedicated Vaccination Clinical Supervisor for every 6 COVID-19 Vaccinators.

***Note 2:** Dedicated Vaccination Clinical Supervisors are not simultaneously responsible for any other roles or processes while supervising COVID-19 Vaccinators.

Note 3: Given this is a new vaccine, DHBs and providers will need to be prepared to adjust site staffing requirements as the reality of administering the Pfizer vaccine will likely vary from these assumptions as delivery progresses.

6.4 Setting Up Mobile Vaccination Teams

You may choose to deliver vaccinations using a mobile vaccination team who will attend a number of different locations rather than being based at a single site. For example, this may be how you deliver vaccinations in aged residential care settings or workplaces.

6.4.1 Workforce considerations

As for fixed sites, you will need to consider how many vaccinators and administrators are needed for each mobile vaccination team.

You will also need to ensure these staff have completed required IMAC training, including CIR training. Follow the existing process to request access to IMAC training. Similarly, you will follow the existing process to request CIR access one the team has completed required training. **Note:** All users who are accessing CIR will need an organisation email address.

6.4.2 Set up the mobile vaccination team in CIR

It is important to correctly set up the mobile vaccination team in CIR so they are linked to a facility and you can track the vaccinations they've delivered. Follow these steps to set them up in CIR:

1. Complete the 'COVID-19 Facility and Site Set-up Details' form (your Regional Account Manager can provide you with a copy), with the following information:
    a. List each mobile team separately using a standard naming convention which should make it easy for you to identify these as mobile teams and for MoH to be able to identify you as the DHB or provider linked to the team. For example, you could use a naming convention of 'CDHB Outreach 1', 'Medpro Mobile 2', or 'ADHB Team 3'.
    b. Identify the facility(s) that will be the 'parent' for the mobile team(s).
2. Send the completed form to your MoH Regional Account Manager.
3. MoH will load the facilities and sites into CIR so you can select them.
4. Ensure your mobile team know which facility/site to which they belong. When they create vaccination events in CIR they'll need to ensure each event record is correctly linked by checking the 'Related Contacts' field under 'Site/Facility'.

6.4.3 Other considerations

When setting up your mobile vaccination team, you should also keep the following considerations in mind:

- **Equipment and Connectivity:** Ensure mobile vaccination teams have the required equipment, both in terms of medical equipment and technology to enable the use of CIR onsite. Check the connectivity at the site before attending.
- **CIR Recording:** As noted above, make sure your mobile team know the name of the facility and team (aka 'site') to select in CIR.
- **Planning:** Establish a clear plan for where the mobile team should be each day and the logistics required for vaccine stock. Make sure there is a record of where the mobile team has been vaccinating and when.
- **Vaccine storage and transport:** All appropriate and standard cold chain must be met when transporting and storing vaccine. Please see guidance on transporting and storing vaccine in the 'Logistics & Inventory Management' section below for more information.

- **Business Continuity:** Ensure you have a business continuity plan to ensure the team can appropriately record vaccination events, e.g. having a stock of printed event forms on hand if you cannot access CIR.
- **Site Readiness:** Refer to the 'Site Readiness Checklist' section above for considerations about completing a dry run with your mobile team before commencing vaccinations.

6.5 Staff Training and Reference Materials

Training will be provided to CIR users and Vaccinators through a combination of eLearning Modules and Quick Step Guides. The Quick Step Guides will be available within the eLearning system, as well as within the Knowledge tab of the CIR for continued availability and reference.

eLearning modules and Quick Step Guides include:

- Working with the COVID Immunisation Register (eLearning)
- COVID-19 Vaccinator Education Course (eLearning)
- COVID-19 vaccination for Prescriber Health Professionals (eLearning)
- CIR Quick Step Guides: Reception, Vaccination, Recovery, Quick Adverse Event, Adverse Event
- Inventory management (eLearning)

In addition to these training materials, staff will have access to a range of reference materials. Please refer to the IMAC website for vaccinator training materials

These include:

- IMAC written resources: https://covid.immune.org.nz/faq-resources/written-resources. This includes COVID-19 vaccinator guidelines and instructions for preparing doses.
- IMAC video resources: https://covid.immune.org.nz/faq-resources/video-resources
- IMAC FAQs: These are available on the IMAC website: https://covid.immune.org.nz/faq
- Immunisation Handbook: The Immunisation Handbook provides clinical guidance for administering vaccines. IMAC has also prepared a COVID-specific chapter in the Handbook. This information is updated regularly. See https://www.health.govt.nz/publication/immunisation-handbook-2020

See 'Ordering Site Collateral' section above for detail on collateral available to be given to consumers

7. Vaccinating Border or MIQF Workers

Staff working at the border or in MIQF are eligible to receive vaccination in Group 1. The COVID-19 Public Health Response (Vaccinations) Order 2021 (the Vaccination Order) requires work at certain places or roles relating to the border to be carried out by workers who have been vaccinated against COVID-19.

As New Zealand moves towards vaccination of the general population, continuing to prioritise border workers for vaccination is of the utmost importance, as they remain at the highest risk of infection and transmission of COVID-19.

7.1 Scheduling appointments for Group 1 Border or MIQF Workers, including those workers subject to the Vaccination Order

MoH creates a list in CIR of new border workers (subject to the Vaccination Order) requiring vaccination on a regular basis.

DHBs can use the CIR Cohort Report to extract details of new border workers using the **'T1 employees'** cohort. The DHB can then liaise with the border worker to schedule an appointment and complete the vaccination event.

While all border workers are Group 1 and require priority vaccination appointments, those border workers (subject to the Vaccination Order) require their first vaccination dose and a booking for their second dose **prior to** commencement of border worker duties. It is recommended that the second vaccination appointment is booked at the time of receiving the first.

To ensure priority vaccination appointments can be made for border workers subject to the Vaccination order DHBs **must** reserve appointment capacity or have an equivalent mechanism to ensure border workers have priority access to vaccination appointments.

7.2 Group 1 Border or MIQF Worker

A border or MIQF Worker is included in Group 1 if they are subject to the COVID-19 Public Health Response (Required Testing) Order 2020 (the Testing Order). Defined as follows:

- A border or MIQF worker is subject to the Testing Order as soon as they perform the duties or functions covered in the Testing Order, or where the employer has a reasonable expectation that the worker may be required to undertake duties that would make them subject to the Testing Order, including NZ Defence Force staff and Police who are eligible for rotation to MIQF;

  or

- If the worker directly interacts with people who are required to be in isolation or quarantine under the COVID-19 order (including those who are isolating outside of an MIQ facility).

7.3 The COVID-19 Public Health Response (Vaccinations) Order 2021

Border and MIQF workers subject to the Vaccination Order are defined as follows:

- Workers at managed isolation and quarantine facilities;
- Workers who transport to and from managed quarantine facilities people required by law to be in isolation or quarantine;
- Workers at managed isolation facilities;
- Airside government officials;

- Government officials who interact with international arriving or international transiting passengers (excluding quarantine free travel passengers);
- Government officials who board, have boarded, or spend more than 15 minutes in enclosed space on board affected ships;
- Government officials who transport persons to or from affected ships;
- Government officials who work at an affected port and who interact with persons required by law to be in isolation or quarantine;
- Cabin crew who travel on domestic flights within New Zealand that carry international arriving or international transiting passengers (excluding quarantine free travel passengers) who have not yet completed isolation or quarantine at managed isolation facilities or managed quarantine facilities.

8. Vaccinating Household Contacts

Household contacts of staff working in border or MIQF are eligible to receive vaccination in Group 1.

8.1 Definition of a Household Contact

A household contact is defined as someone who usually resides in a household or household-like setting with a border or MIQ worker. Household contacts are eligible regardless of whether they are related or unrelated people and it includes people who may reside part-time in the household. Partners and dependents of eligible workers should be included (for dependents 16 years or older as per MedSafe approvals).

8.2 Collecting Household Contact Information

Channel	Description	Timing
 **Digital**	In the first instance, MoH will directly contact staff with eligible household contacts using information in the Border Worker Testing Register. Contact will be made with eligible staff to invite them to provide details of their household contacts (this will include an approximate geographic location field to support delivery planning).	Prior to event and ongoing
 **Phone 0800 2VAXCOVID**	An 0800 phone line – 0800 2VAXCOVID – will also be available for workers with an eligible household contact to call. This will be operated from 8am to 8pm. Multiple language options will be available. Callers will be verified and asked to provide details for themselves and their household contacts. These details will be passed on to DHBs for scheduling per the following section. Please provide the 0800 2VAXCOVID number in your engagements with Border or MIQF workers so they can proactively supply household contact information.	Prior to event and ongoing
 **During current interactions**	DHBs currently have a presence in the border and MIQ facilities and may choose to collect contact information during their current interactions with border and MIQ workers. For example, this may include collecting household contact information at the next mandatory test.	During regular testing
 **At the time of vaccination**	At the time of vaccination, the vaccination team should remind border and MIQ workers to submit the details of their household contacts. The first preference is for consumers to use the digital link to complete the online form. The hard copy form should only be provided as a back-up for completion if the consumer cannot access the online form or is unable to contact 0800 2VAXCOVID. Where hard copy forms are completed, administration staff must transfer these details into an online form for MoH to collate. This will reduce the privacy risk associated with holding hard copy information and enables sharing of information about household contacts if they are living in different regions. Any hard copy forms must then be destroyed.	At event

8.3 Scheduling appointments

Responses will be compiled by MoH and subsequently shared with the appropriate DHB via a report. DHBs can then liaise with the household contact to schedule an appointment and complete the vaccination event.

MoH intends to move to a self-service reporting model to enable DHBs to generate the report with household contact details rather than MoH sending it out.

8.4 Vaccinating Household Contacts without appointment

There may be instances where household contacts accompany workers to their vaccination. If this happens, individuals should be provided with a digital or hardcopy form to complete in order to enable the scheduling of their vaccination. Note that household contacts will need to provide information that provides a link to an eligible worker (i.e. name and phone number) and be loaded into CIR manually.

In some cases, it may be possible to provide a vaccine in a 'walk-in' scenario. This will be at the discretion of the site manager based on their scheduled vaccine supply.

9. Running a Vaccination Site

9.1 Booking and Scheduling

Arrangements for the booking and scheduling of Group 1 consumers, including household contacts, will take place at the DHB or provider level. This will include booking and scheduling appointments for consumers to receive the second dose of the Pfizer vaccine. This should also include re-scheduling second dose visits if needed and providing a mechanism for people to reconfirm their appointment time (e.g. if they lose their appointment card).

At present, a national booking system is not available. MoH will provide more details about the national booking system as soon as possible. It will not be mandatory for DHBs or providers to utilise this system.

9.1.1 Pre-loading immunisation event records in CIR

CIR is linked to consumers' NHI numbers, meaning anyone with a NHI will be automatically available in CIR, i.e. they will have a CIR profile. Where consumers are in the Border Worker Testing Register (BWTR), MoH will extract that information to create immunisation event records (or 'cases') and add these to the consumer's CIR profile.

If consumers aren't in the BWTR, vaccinators or site administrators can add the immunisation event record/case to the consumer's profile on site at the time of vaccination.

9.1.2 Booking second doses

You must arrange for consumers to return for a second dose of the Pfizer vaccine at least three (3) weeks after receiving the first dose. Doses can be booked for any time on day 21; you do not need to count exactly 21 days of 24 hours between doses. You should arrange the second dose booking as close as possible to the 3-week mark.

9.2 Preparation of Doses

The Pfizer vaccine comes as a concentrate and **must be diluted on site** following the instructions provided by the Immunisation Advisory Centre (IMAC). These instructions will be included in vaccine shipments and are also available on the IMAC website. **Note:** These instructions were updated on 29 March 2021. Please ensure you are using the most recent version.

As noted in IMAC's instructions for preparing the Pfizer vaccine, the vaccine should be brought to room temperature prior to dilution. It should not feel cold to the touch. The actual time to get the vial to room temperature will vary depending on when you take vials out of the fridge and the temperature of the room – approximately 30 minutes should be sufficient time.

Please note the Pfizer vaccine is fragile and **must not be shaken** during preparation. However, if the vial has been fully thawed you can gently invert the vial 10 times to reduce condensation.

If during the preparation of the vaccine a foreign body or discolouration is identified for example, a black particle, this vial should be discarded as per section 8.7.2 and recoded as an "open vial-quality issue" in CIR.

Once the vaccine has been diluted, it **must be administered within 6 hours**. Any prepared doses not used within this time period must be discarded. Prepared doses cannot be transported to other sites.

For quality and safety purposes, after diluting the vaccine, it is recommended that each vial and/or syringes (made from that vial), are labelled with:

- Diluent Name
- Date and time after dilution

- Expiry time after dilution

You should only draw up one vial at a time and each vaccine from that vial should go into one container with the original vial for vaccine delivery. Do not mix doses from different vials.

You **must avoid exposing the vaccine to direct sunlight or UV light at all times** (when both a concentrate and prepared).

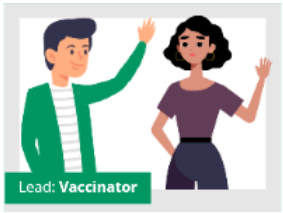
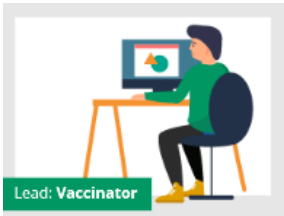
During the preparation of the vaccine standard local Infection Prevention and Control (IPC) policies should be followed.

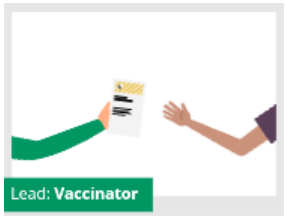
9.2.1 Number of doses per vial

The expected number of doses from each vial remains at 6 but there is technically enough vaccine in a vial to enable you to draw up 7 dose of vaccines using LDS needles. Provided you are totally confident that you have measured your saline correctly for dilution, each dose of vaccine has the full 0.3mls, and you are drawing up and giving using the same needle as instructed, then it is safe to use the vaccine in the 7th dose.

Note: Insufficient volume of diluent may be detected by identifying you have drawn up less than 6 doses from the vial. If this occurs, quarantine and discard all doses from that vial. This error must be documented as waste in CIR and reported as an incident in the local organisation's quality and safety reporting system.

9.3 Pre-Vaccination Steps

Step	Action
 **Greet consumer & conduct COVID-19 health check**	On arrival at the vaccination site, the vaccinator/site administrator will greet the consumer and ask the consumer whether they have any COVID-19 symptoms as per standard site practices. Please note: • People who have symptoms of COVID-19 should be advised to stay at home and get a test. They are able to be vaccinated once they have a negative test result and symptoms are mild only. • People who are significantly unwell are advised to wait until they are better before getting the vaccine; however, note that mild symptoms are not a contra-indication. People in this situation are advised to discuss their symptoms with their GP or vaccine provider. • People who have been advised to self-isolate, stay at home or are waiting on a test result, should have their appointment deferred. Please see below section 'Vaccination Site Screening Questions' for additional screening questions.
 **Verify consumer's identity**	The vaccinator/site administrator will also verify the consumer's identity using name, DOB and address and locate their record in CIR. **Note:** Photo ID is not required to confirm the consumer's identity.

Step	Action
 **Provide collateral**	The vaccinator/site administrator will provide the consumer with the COVID-19 vaccination information and consent pack, which includes the 'Getting your COVID-19 vaccine: What to expect' factsheet, consent form, privacy statement and 'After your immunisation' factsheet. You may also choose to provide the COVID vaccine FAQs sheet, which is available on the MoH website. You may also display the privacy statement in the reception area as well as supplying the information in hard-copy.

9.3.1 Vaccination Site Screening Questions

We encourage you to screen both staff and consumers for risk of exposure to COVID-19 and COVID-19 symptoms. Screening is critical to breaking the chain of transmission of COVID-19 and maintaining staff and consumer safety. We recommend screening questions to include:

1. Do you have symptoms of COVID-19? (these are available on the link below)
    - Link to: COVID-19 Case Definition
    - If a client has any symptoms suggestive of COVID-19, defer vaccination and do not permit entry to the site. Recommend they get a test and self-isolate pending the result.
    - If no symptoms, continue to the next question.
2. Have you been to any Contact tracing locations of interest within time periods of concern?
    - Link to: Current Contact Tracing Locations of interest
    - If an individual has been at any locations of interest within the defined time periods; defer vaccination, do not permit entry to the site, and advise them to follow recommendations and guidance from the Ministry of Health/public health services.
    - If no, proceed to the next question.
3. Have you been requested to stay at home or to self-isolate?
    - If yes, defer vaccination and do not permit entry to the site. Recommend continuing to follow the stay at home/self-isolation plan.
    - If no, continue to next question.
4. Are you currently waiting on a COVID-19 test result?
    - If yes, defer vaccination and do not permit entry to the site. Recommend re-booking once a negative test result has been received, and they have been told they no longer need to stay at home/self-isolate.
    - If no, proceed to vaccinate as per the Operating Guidelines.

Note: In the event of COVID-19 Alert level changes, additional advice will be formulated by local Public Health Units and the Ministry of Health.

9.3.2 Where the consumer does not have an NHI number

If a consumer doesn't have an NHI in CIR, you should confirm that the consumer is in the eligible cohort to receive the vaccine and then create a new NHI number for them. If you have the ability to create an NHI number in Health UI, please do so. Alternatively, you can contact the MoH contact centre on 0800 855 066 to request an NHI number be set up. If you call the contact centre, make sure you:

- Provide the payee number for your DHB or hospital
- Identify yourself as a COVID vaccination clinic
- Provide your name

Once the NHI is created, you'll need to make sure it is linked to CIR using the 'NHI Retrieval' function. Retrieving the NHI will create a Person Profile in CIR and you can then create immunisation case records as normal.

Note: It is not mandatory to collect information on the consumer's residency status when setting up new NHI numbers. Previous experience has demonstrated that collecting residency information can be a barrier for consumers both in their uptake and receipt of healthcare services.

9.3.3 Where the consumer has received vaccination overseas

In some instances, individuals may have received a COVID-19 vaccine overseas (which may not be of the Pfizer vaccine). Clinical protocols for all of these situations are still under discussion; however, if the consumer had dose 1 of a two-dose regimen (Pfizer or other two-dose vaccine), they are able to receive the Pfizer COVID-19 vaccine as dose 2 provided it is at least 4 weeks after their overseas vaccination. Please consult 0800 IMMUNE or the IMAC website for specific clinical advice.

The consumer must provide evidence of their overseas vaccination (e.g. a vaccine receipt card or other documentation) and you must create immunisation records in CIR and upload the evidence they have provided.

Note: The CIR record of the New Zealand-based dose administered is automatically notified to the individual's GP through the existing CIR GP notification functionality. In the next CIR release (available June 3), new functionality will be added to allow notification of overseas vaccination to GPs. Any overseas-based event records created before 3 June will be retrospectively picked up and notified to the consumer's GP.

9.4 Vaccination and Observation

9.4.1 Obtaining informed consent

Prior to administering the vaccination, the vaccinator must obtain informed consent per the Code of Health and Disability Services Consumers' Rights. This must be documented in the CIR and may be **verbal or written**, as appropriate for the consumer being vaccinated, as per the requirements below:

a. The vaccinator or an administrative support person must record the consumer's consent to receive the vaccine in CIR. If the person does not wish to receive the vaccine, record their decline in CIR.

b. Written consent must be obtained for Group 1 consumers (Border workers and their household contacts). These forms must be uploaded to CIR.
Note: You must use the official MoH consent form to obtain consent from individuals in Group 1.

c. Written consent must be obtained where there are significant risk of adverse effects to the consumer, per clause 7(6c) of the Code

d. Written consent may be used if this is the provider's or vaccinator's preference, for example, in aged residential care settings.

Where written consent is recorded under points c and d above, these forms do not need to be uploaded to CIR; instead the provider is responsible for ensuring forms are stored as part of that person's clinical record.

Where a consumer is not competent to make an informed choice and give informed consent for the vaccine, someone who has the legal right can make decisions on the consumers behalf. This is a legal guardian or someone who currently holds Enduring Power of Attorney for personal care and welfare.

For more information on obtaining informed consent, please see Chapter 2 of the *Immunisation Handbook*.

9.4.1.1 Uploading Group 1 written consent forms

Written consent forms signed by Group 1 consumers must be uploaded into CIR. This may be managed on-site or by a centralised administration team. Given the information on the written form contains personal information, **forms must be held and transported securely at all times** (e.g. in a locked cabinet or drawer or in a tracked courier bag or other secure container if transported between locations).

To upload the forms, the administrator must scan each form to their computer, locate the consumer's CIR record, and then upload the form to the consumer's CIR record. The administrator must then delete the local copy of the form on their computer and securely destroy the written form. If needed, the written form may be kept for a few days or weeks to check for inaccuracies in transcribing before they are destroyed.

Note: Instructions for uploading files to CIR are included in the CIR eLearning module.

9.4.1.2 Variations to consent forms

As noted above, where written consent is obtained for Group 1 consumers the official MoH COVID-19 vaccine consent form must be used. This is available via the MoH Dropbox. **Note:** As of 6 May 2021, there is only one MoH consent form. The Group 1a version of the consent form has been withdrawn.

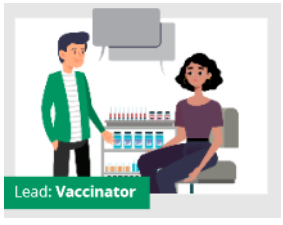
If you choose to use a variation of the MoH consent form for other Groups, you must include the standard information on the MoH form, that is the 'Please let your vaccinator know' bullet points as well as the informed consent declarations. You must submit your consent form to MoH for review and approval before making it available for use.

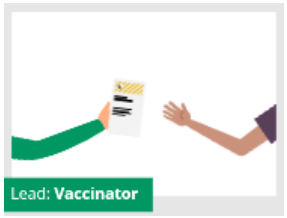
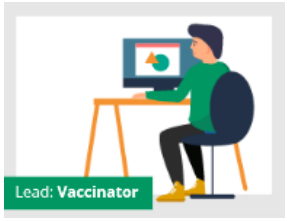
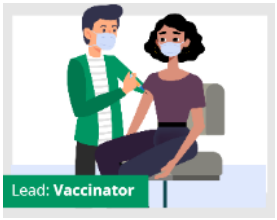
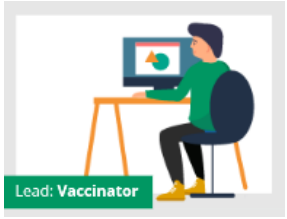
9.4.2 Recording vaccination information in CIR

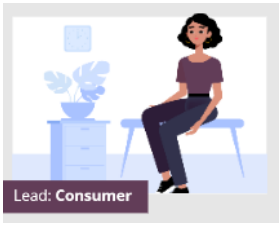
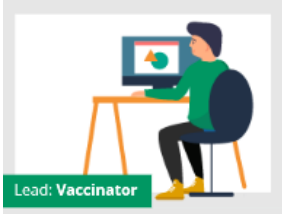
You must ensure a complete and accurate record of the vaccination event is entered into CIR at the time of the vaccination.

If this is not possible (e.g. if CIR is unavailable or if you are vaccinating at a location without sufficient internet connectivity), then you must implement an administrative process to ensure information is entered into CIR on the same day as the vaccination event. You must ensure this essential clinical information is not lost and is transcribed correctly.

9.4.3 Vaccination process

Step	Action
 **Complete a pre-vaccination clinical assessment**	The vaccinator undertakes a pre-vaccination clinical assessment. This encompasses whether the consumer has medical reasons why they should not receive the vaccine, any history of allergy, whether they had an adverse event after receiving the first dose of the COVID-19 vaccine, any current symptoms and other relevant precautions. The outcome of this clinical assessment must be recorded in CIR (in the 'Medical screening' section). **Note:** If you record the consumer as medically unfit to receive the vaccine, CIR will prompt you to either cancel or reschedule the immunisation event. If the consumer is temporarily unable to receive the vaccine (e.g. they are unwell today), you should select 'reschedule' to ensure you can use the same CIR case record in future to capture details of the first and second doses. You should only select 'cancel' if the consumer will *never* be able to receive the vaccine. Cancelling the event record means you cannot go back record a first or second dose on this record in future.

Step	Action
 **Obtain informed consent**	The vaccinator (or vaccinator support person) must obtain the consumer's informed consent to receive the vaccine prior to the administering of the vaccine. Where appropriate, consent may be given by a proxy such as a guardian or person with power of attorney. **Note:** IPC guidance must be observed when dealing with hard-copy consent forms and obtaining consent. For example, consumers should use hand-sanitiser before or after handling a pen to sign the form or bring along their own pen.
 **Record consent in CIR**	The vaccinator or an administrative support person must record the consumer's consent to receive the vaccine in CIR. If the person does not wish to receive the vaccine, record their decline in CIR.
Check vaccine	Check the label and confirm that the 'expiry time after dilution' (6-hour window) has not expired.
 **Administer vaccination**	Administer the vaccination. **Note:** Use your clinical judgement to determine if a longer needle is required (38mm). Use of shorter needle has the potential to deliver the vaccine subcutaneously as opposed to intramuscularly, which has the potential to underdose. For more information on needle length, refer to the Immunisation Handbook. IMAC are creating clarified preparation and administration guidance for this situation, including the importance of priming. MoH will distribute a stock of 38mm 21G needles and is also investigating procuring a supply of 38mm 23G needles for distribution.
 **Record vaccination information in CIR**	Once the vaccination is complete the vaccinator or administrative support person must update the consumer's record in CIR to include: • The batch and sub-batch number, e.g. AB1234-567 (the first part is the batch number, the second part is the sub-batch number. These are recorded on the vaccine box.) • Details of the injection site and the date and time of the vaccination event.

Step	Action
 **Consumer waits 20 minutes in observation area**	The consumer must remain on site under observation for at least 20 minutes. If the vaccinator determines it necessary, they **may** ask the consumer to wait for longer than 20 minutes, for example, if the individual is in a rural or remote area or has a history of anaphylaxis. The vaccinator or site administrator will provide the consumer with a card recording the date/time of their vaccination and the date when they will be expected to receive the second dose of the Pfizer vaccine. **Note:** This vaccination receipt card currently serves as the proof of vaccination and must be provided to the consumer. Please encourage consumers to retain their receipt card and keep it somewhere safe or take a photo of their receipt card. MoH is exploring a digital certificate for proof of vaccination.
 **Record exit in CIR**	The site administrator/vaccinator must record the time of the consumer's exit from the site in CIR.

9.4.4 Planning for Adverse Events

Some consumers may have a history of allergy or hypersensitivity following administration of vaccines or injectable medicines that warrants additional monitoring at the time of receiving their first dose of the vaccine. Similarly, some people have experienced an adverse event after receiving their first dose of the vaccine that warrants clinical monitoring at the time of the second dose.

MoH expects you to have appropriate protocols, equipment, settings and workforce in place to support those who may require enhanced care following vaccination. For example, you may wish to arrange this type of enhanced care at the time of booking or prior to these individuals attending a vaccination site.

It is recommended that you use simulation scenarios to prepare staff to respond to adverse events.

9.4.5 Adverse Events during observation period

If the consumer has an adverse event during the 20-minute observation period at the vaccination site, appropriate medical attention must be provided. The on-site adverse event must be recorded in CIR to enable reporting on adverse reactions to the vaccine.

For more information on managing medical emergencies and anaphylaxis, please see section 2.3 of the Immunisation Handbook.

Adverse events should be notified to the site lead Clinician, who can then undertake a clinical review and determine appropriate actions with the site manager (e.g. pausing vaccinations for a time if needed).

The adverse event must be recorded in CIR. The Centre for Adverse Reaction Monitoring (CARM) will then undertake further investigation and provide any additional guidance to the consumer and site as appropriate.

9.4.6 Adverse Events after observation period

If the consumer has an adverse event after the observation period/when they've left the vaccination site, they will be advised (in the 'After your immunisation' flyer) to contact Healthline and submit an adverse reaction

report to the Centre for Adverse Reaction Monitoring (CARM). A dedicated COVID-19 Vaccine Adverse Event Report is available on the CARM website. This may be completed by the consumer or a health practitioner.

9.4.7 COVID-19 treatment injury claims

ACC are sharing advice with providers about lodging ACC claims for a physical injury resulting from a COVID-19 vaccination. Such injuries may be covered by ACC if the criteria for treatment injury are met. Under ACC legislation, the injury must be clearly caused by the vaccination and must not be a necessary part or ordinary consequence of the treatment.

For example, inflammation around the site of the injection is common with COVID-19 vaccination (an ordinary consequence) and is unlikely to be covered. Infections (such as cellulitis or septic arthritis) due to the vaccination, and anaphylaxis resulting in injury are not ordinary consequences and are likely to be covered.

If a patient has an injury that meets these criteria, they may require further treatment or support. If so, providers would submit an ACC2152 treatment injury claim form should be lodged with ACC as well as an electronic or manual ACC45 injury claim form.

Providers will need to include the vaccine brand and dose number (i.e. for the Pfizer vaccine, whether it is the first or second dose).

Note: Health providers should keep good clinical records of reactions and complications and arrange appropriate clinical management and follow up. Treatment Injury Claim Forms can be completed at the time or at a later date (e.g. within months). Time should be taken to obtain consumer consent for a claim to be lodged with ACC, as it involves providing their personal and private information to ACC. Consumers should be reassured that the health system will manage their treatment regardless of an ACC claim.

9.5 Recording Vaccine Errors

A vaccine administration error is any preventable event that may cause or lead to inappropriate use of a vaccine or consumer harm. Administration errors can occur at any stage of the vaccination process (e.g. storage or handling, site/route of administration or dosage given).

If a vaccine administration error occurs:

- Inform the consumer(s) involved
- If guidance/advice is needed, consult IMAC on 0800 IMMUNE (466 863), option 1 (Health professionals) and then option 2 (COVID vaccinator support)
- Record the error in CIR under Adverse Events 'error' to enable reporting on vaccine administration errors.
- Determine how the error occurred to allow strategies to be implemented to prevent it from happening again.

Providers should report all COVID-19 vaccine administration errors – even those not associated with an adverse event. On submission of the Adverse Event/Medical Error form in CIR, the data will go to the medical assessment team at the Centre for Adverse Reaction Monitoring (CARM). The medical assessment team review Adverse Events and Medical Errors to help inform any follow up required. Adverse Event and Medical Error reports also inform vaccine safety monitoring.

9.6 Administering Leftover Vaccines

To minimise wastage, MoH recommends you plan a back-up or stand-by list of consumers that aligns with the sequencing framework. If you have leftover diluted and/or drawn vaccine left at the end of the day/week that will expire before the next clinic, we encourage you to administer these individuals on your stand-by list.

MoH does not require visibility of your stand-by list; you can manage this list as needed to align with the sequencing framework as best you can.

9.7 Disposal of Consumables, Vaccine and Vaccine Packaging

eLearning modules will be available on vaccine disposal alongside other inventory management topics outlined below.

9.7.1 Disposal of consumables

DHBs and providers are responsible for the disposal of consumables. Consumables should be disposed of according to existing procedures (e.g. disposal into sharps bin and/or biohazard bags). Follow your local procedures to arrange collection of the sharps bin and other medical waste.

9.7.2 Disposal of damaged, empty and expired vaccine vials

As part of your site preparations, make sure you contact Interwaste to request a vial disposal bin to be delivered to the site. You can contact them on 0800 102 131 (their call centre is available from 8am-5pm weekdays).

Interwaste will then provide you a 20 litre-sized container in which to dispose empty, broken or damaged vials. When the container is almost full, you can contact Interwaste on 0800 102 131 to arrange for pick-up. Interwaste will deliver a new disposal container at the same time and remove the existing container so they can destroy the vials in an appropriate manner.

Make sure you keep the lid of the Interwaste disposal container closed when not in use.

Figure 1: Interwaste disposal bin

9.7.3 Disposal of vaccines drawn up but not administered & empty vaccine syringes

Vaccine doses that have been drawn up but not administered must be disposed of in the sharps bin provided. Similarly, empty/used vaccine syringes can be disposed of in the sharps bin.

9.7.4 Disposal of vaccine packaging

You must ensure all packaging the vaccine is sent in is destroyed so packages cannot be replicated.

Once all vials in a packet have been used, black out all vaccine-related information on the label using a permanent marker. The vaccine box must be securely destroyed. You can dispose of it in a secure document destruction bin if one is available or a biohazard bag. Packaging must not be disposed of in household waste collection or recycling centres. If you need additional biohazard bags, please advise MoH Logistics for your next consumables order.

9.8 Operational Reporting

Sites must ensure vaccination events are recorded in CIR at the time of administration to enable accurate data for operational reports (such as number of vaccinations completed and other trend data).

Providers will need to report significant events on sites (e.g. significant adverse reaction, protest etc) to MoH on a daily basis.

Using the CIR Inventory Portal, providers must ensure that Facility stock on hand and any stock movements from Facility to Facility, or Facility to Site, are recorded on a daily basis.

DHBs or providers may wish to collate daily reporting back from sites on inventory and/or operations to aid in supply information back to MoH.

Please contact your regional liaison if you have feedback on the immunisation process or recommendations for operational improvements.

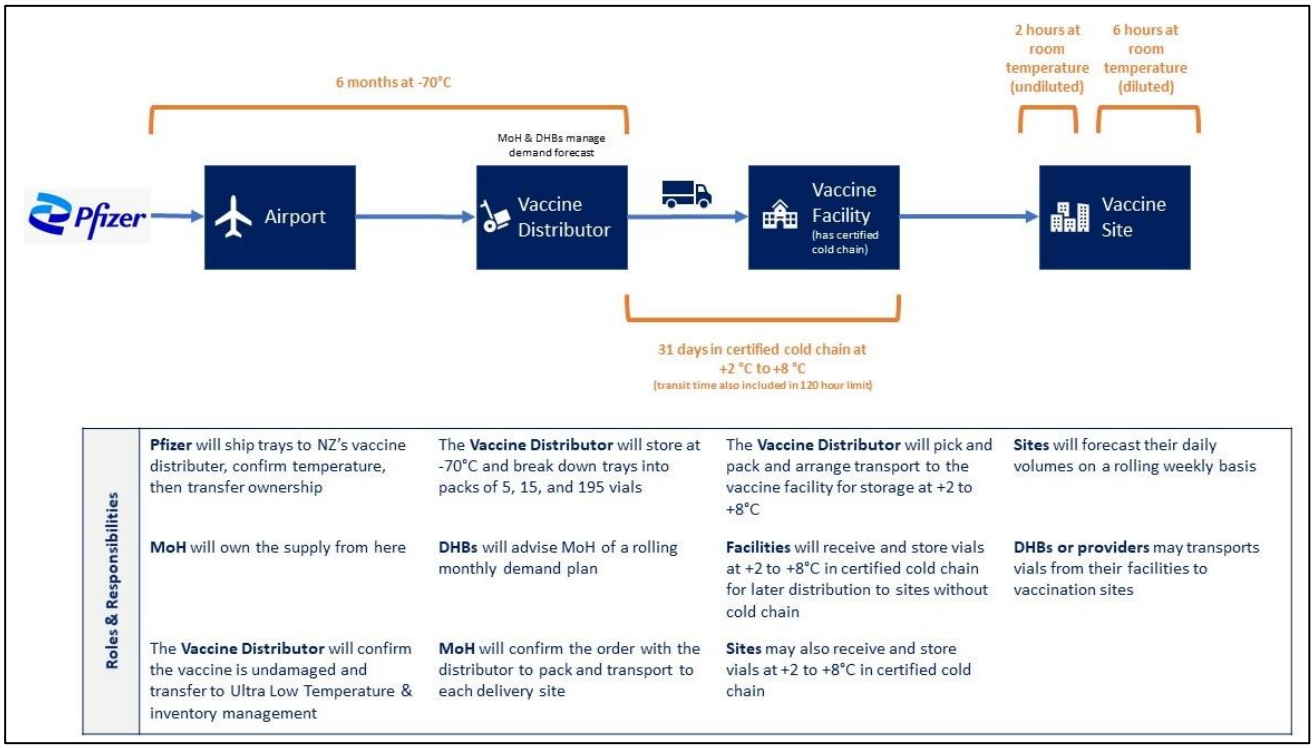
9.8.1 Reports available to DHBs

COVID-19 vaccine reporting is linked to the NHI database, meaning you can request existing NHI data fields (e.g. ethnicity) to track vaccination rates and meet other reporting needs.

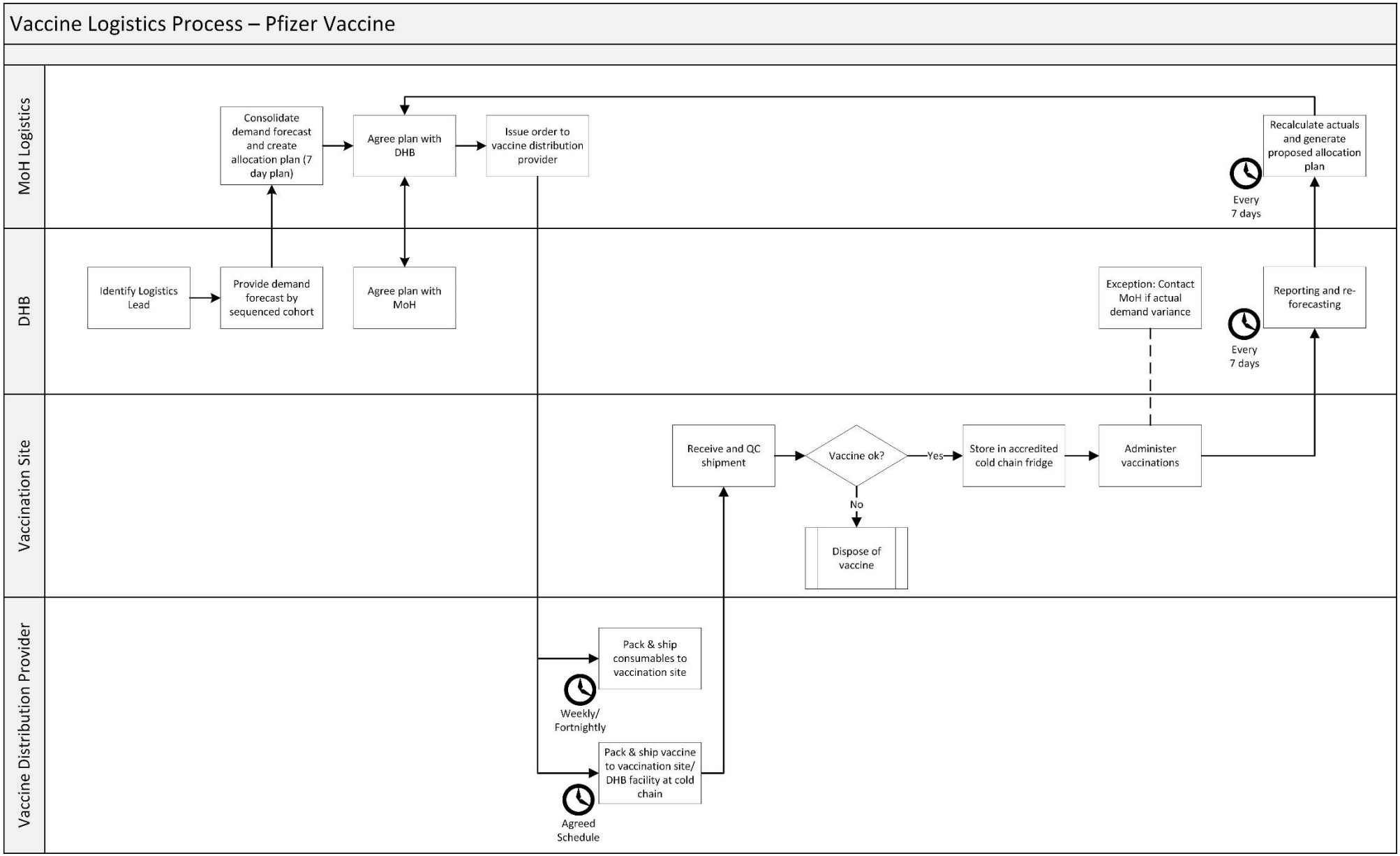
To request vaccine reporting, contact your DHB or provider reporting team, who will then submit your request to the MoH reporting team. Once the report is prepared, it will be available in CIR as both a dashboard and downloadable report that will be updated in real-time. Note that if you need data for multiple DHBs, you must specify this in your request.

10. Logistics & Inventory Management

MoH will maintain the COVID-19 Vaccination & Immunisation Register (CIR) Logistics module to support ongoing monitoring of inventory and demand. The image below shows the current process for distributing the vaccine to vaccination sites.



10.1 Vaccine Logistics Process Overview



10.2 Demand Planning and Vaccine Ordering

10.2.1 Site and facility set up for vaccine delivery

Site and facility information must be provided to MoH five (5) days in advance of any initial deliveries. Please use the 'COVID-19 Vaccine Facility and Vaccination Site Set Up Details' form to submit site or facility details – your MoH Regional Area Manager will provide you a copy of this form.

Return the completed form via email to your Regional Area Manager and cc the MoH Logistics team.

10.2.2 Demand planning

DHBs or providers must share a demand plan for the forward four weeks at a facility/site combination level. This plan should represent the expected number of vaccination events due to take place each day in each location.

The mechanism for submitting the forward demand plan is through the CIR Inventory Portal. Please contact your local lead user if you require access to the system.

We request that forecasts are updated at least once a week.

10.2.3 Vaccine ordering

Vaccines are expected to be delivered weekly.

Any orders that are placed prior to 10am (Day 1) will be delivered the next day (Day 2). Any orders placed after 10am will be delivered on Day 3 or delivered as an urgent order (see the 'Urgent consentvaccine orders' section below).

Facilities should consider the size of the packs they are ordering and their ability to break down packs to avoid unnecessary vaccine movement or wastage.

Use the below table template to request vaccine. Send this request by email to the MoH Logistics team with the subject line 'VACCINE ORDER – [Name of Provider]'.

Order for delivery	xx/xx/xx			
	Vaccine			**Consumables packs**
Facility	**5 packs**	**15 packs**	**Full tray**	
Facility 1	x	x	x	Y/N
Facility 2	x	x	x	Y/N
Facility 3	x	x	x	Y/N

10.2.3.1 Urgent vaccine orders

From time to time, there will be exceptional circumstances where sites experience unexpected demand spikes for immunisations, and stock of vaccines will need to be replenished to support the site through to their next agreed delivery.

If you need to place an urgent order:

1. Use the table template above to place the order in an email.
2. Forward the email order to your SRO for approval. All out of plan orders must be **pre-approved by the SRO** prior to being submitted to MoH.

3. The SRO will choose to approve or reject the order.
4. If the order is approved, the SRO will forward the order (with their expression of approval) through to the MoH Logistics team with the subject line 'VACCINE ORDER – [Name of Provider]'.

All urgent orders need to be received via email directly from the SRO with their approval.

MoH will review the order and determine if it is possible to fulfil the order. The Logistics team will contact both the SRO and Logistic lead to confirm whether the order can be fulfilled and, if it can, when delivery will occur.

Note: While we will endeavour to accommodate any out of cycle vaccine requests, the complexity of thawing and re-packing vials means MoH cannot guarantee that all urgent orders will be fulfilled.

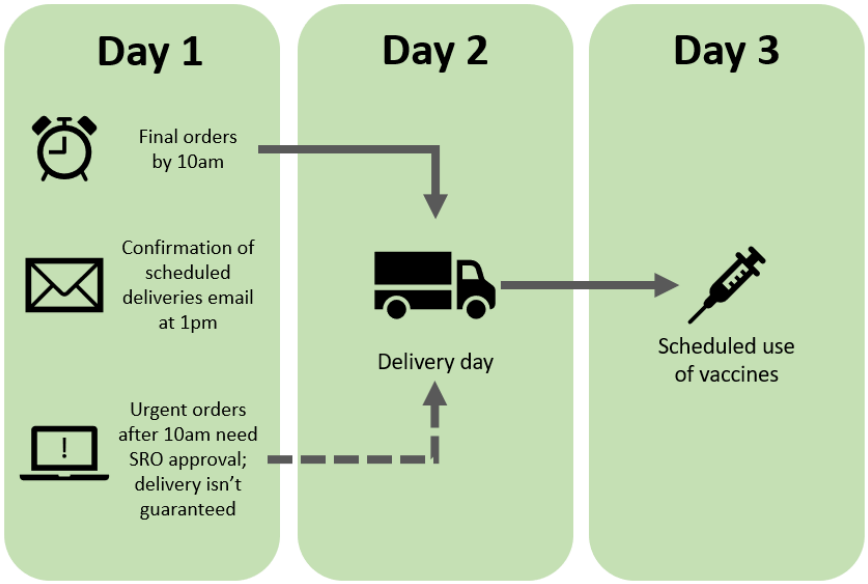


Figure 2: Vaccine Ordering Process

10.2.4 Consumables packs

MoH will provide consumables required to administer the Pfizer vaccine. You can order consumables packs to be shipped directly to sites alongside vaccine deliveries. The consumables packs include everything needed to administer the COVID-19 Pfizer vaccine.

There are 2 packs available based on the size of vaccine order:

1. **Pack 1 for 100 Doses:** MoH will calculate the number of packs that will be sent with each order by rounding up the number of doses ordered to the nearest 100 (based on 6 doses per vial) and send the corresponding number of packs. For example:
    a. You order 40 vials. MoH will send 3 packs (40 vials equate to 240 doses, rounded up to 300).
    b. You order 15 vials. MoH will send 1 pack (15 vials equate to 90 doses, rounded up to 100).
    c. You order 90 vials. MoH will send 6 packs (90 vials equate to 540 doses, rounded up to 600).
2. **Pack 2 for Full Tray:** For each tray you order, we'll send a pack containing consumables to cover 1,300 vaccinations. Based on 6 doses per vial, a tray providers 1,170 doses. Based on 7 doses per vial, a tray providers 1,365 doses.

Please indicate if you would like consumables packs to be sent with your vaccine order using the amended order form in the 'Vaccine ordering' section above.

Consumables packs contain the following items:

Item	Material number	Notes	Pack 1 100 vaccinations	Pack 2 Full tray
25G Needle	1165011	Drawing needle for saline - 1 syringe per vial dilution	20 (partial pick)	200 (2 cartons)
3ml Syringe	1165009	Drawing syringe for saline - 1 syringe per vial dilution	20 (partial pick)	200 (2 cartons)
LDS Needle	1165446	Administering needle - 1 per dose	100 (1 carton)	1300 (13 cartons)
1ml Syringe	1165008	Administering syringe - 1 per dose	100 (1 carton)	1300 (13 cartons)
Antiseptic Swabs	1165005	2 swabs per injection	200 (1 carton)	2600 (13 cartons)
Non-Woven Swab	1165004	2 swabs per injection	200 (2 cartons)	2600 (26 cartons)
5ml Saline	1165012	1.8mL per vial	20x5ml (1 carton)	
10ml Saline	1165013	1.8mL per vial		200x10ml (4 cartons)
Plasters	1165006			1000 (4 cartons)

Consumables packs have the following sizes and weights:

Pack Type	Carton Size	Carton Weight
Pack 1 – 100 Doses	250 x 250 x 200mm	1.2kg
Pack 2 – Full Tray	510 x 380 x 280mm	7.45kg
	510 x 380 x 280mm	8.35kg

10.2.5 Ordering other MoH-supplied consumables

Any consumables not directly linked to the administration of the vaccine can be ordered by emailing the MoH Logistics team. This includes sharps bins, bio bags for waste disposal, or 21G 38mm needles.

In rare circumstances you may need to order individual items to top up stock (e.g. boxes of plasters). You can do this via MoH Logistics. Such stock will be shipped through a standard courier network, with delivery between 2-4 days from the time of order.

10.2.6 Personal Protective Equipment (PPE) ordering

PPE for vaccination sites can be ordered from the existing PPE Portal via HealthCare Logistics or Onelink. The PPE provided will be based on current COVID-19 Alert Level settings. Healthcare providers hold contingency stock of PPE which can be utilised in the event of Alert Level changes.

If you are a new provider or currently do not hold contingency stock, please contact COVID.healthsupplychain@health.govt.nz to discuss your requirements.

10.3 Delivery to Sites

10.3.1 Delivery security

MoH will organise secure transportation of the large quantities of vaccine from the vaccine distribution provider to the cold chain storage facility (e.g. DHB facility or vaccination site) using a MoH-contracted courier and security firm.

If the vaccine is transported to a DHB cold chain storage facility, the secure transportation of the vaccines from that facility to the vaccination sites is the responsibility of the relevant DHB or provider.

Figure 3: External Packaging

If you are transporting vaccine from a local facility to the vaccination site, the unique circumstances of these transportations should be considered in the site risk assessment. MoH recommends that if couriers or authorised persons (e.g. vaccinators, administrators, security personnel or others) are conducting the transport there should be direct travel (no transit points) to the vaccination site.

Note that there should be a local procedure in place to ensure anyone responsible for transporting vaccine is identified as the locally-agreed person responsible for vaccine transportation (i.e. the DHB or provider must have confidence they are handing over the vaccine for delivery to the correct person). There is no requirement for this to be a vaccinator specifically.

Figure 4: Credo Cube

10.3.2 Delivery schedule

Vaccine will be shipped to agreed locations on a schedule agreed with DHBs or providers. This means that a site with higher volumes can receive more regular shipments while lower volume sites or sites only operating on one day a week may choose to receive only one shipment per week.

Each site receiving shipments from MoH will receive a notification containing details of the amount of vaccine and/or consumables due to be delivered the following day. Delivery tracking will be managed centrally by MoH.

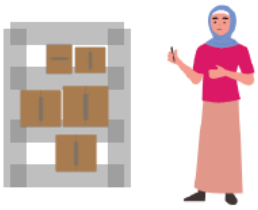
10.3.3 Delivery temperature

The vaccine will be shipped under cold chain conditions at +2°C to+8°C from the distribution provider in Credo Cubes.

Vaccines will be labelled with a use-by date once they are removed from ULT -90°C to -60°C and begin thawing. This date will be **31 days** after removal from ULT. The use-by date/time will be on the vaccine carton.

10.4 Site Delivery and Receipt Process

Step	Action
 **DHB/Provider Logistics Lead provides site contact & delivery details**	Five days prior to the site commencing vaccinations, the DHB or Provider Logistics Lead must provide MoH with a site contact (a named role and a phone/mobile number) and detailed delivery instructions, including address and any special instructions (such as separate entrances etc). This information is submitted using the 'COVID-19 Vaccine Facility and Site Set-Up Details' form. Your regional liaison will share this form with you. The site contact must be regularly available on site to accept deliveries to minimise the admin involved in changing the site contact person (Notify urgent site contact changes to MoH Logistics). MoH recommends that individuals handling vaccines are cold chain accredited; however, this is not a requirement.
 **Vaccine distribution provider packs and ships vaccine**	The vaccine distribution provider will pack and ship the vaccine under cold chain conditions in Credo Cubes at +2°C to+8°C.
 **Site contact receives the package**	The courier will hand the package to the site contact. Before signing for the package, the site contact will: • Confirm the Credo Cube is addressed to them/their site • Provide their identification to the courier for the courier's confirmation • Conduct a check of the order immediately while the courier is present (see below)
 **Site contact checks the temperature logger**	The site contact must check the temperature datalogger included in the Credo Cube to confirm whether a temperature excursion has occurred in transit. Retrieve the temperature logger immediately and do not attempt to stop it. Check the temperature logger as soon as you remove it. The temperature logger will have a green light which flashes once every ten seconds if the temperature has remained within limits or a red light which flashes once every ten seconds if an excursion has occurred. Where an excursion has occurred the site contact must quarantine the shipment in cold chain conditions while the logger is returned to the vaccine distribution provider for reading. The site contact must call the MoH Logistics team. The Logistics team will talk the site contact through the actions to be taken, such as urgent orders being placed and what will happen once the temperature data has been read. In this situation, the site contact will **not** sign for the package with the transport provider and it will be returned to the distribution provider.

Step	Action
 **Site contact conducts visual check**	The site contact will open the Credo Cube and the internal vaccine packaging and conduct a visual check of the vials in each package to ensure vials are intact. Broken vials or waste needs to be recorded in the CIR Logistics module, but only to the unopened vial stage. Vaccine wasted in opened vials does not need to be recorded in the CIR Logistics module. Please see the Standard Operating Procedures in the 'Inventory Orders' section on how to record vial consumption and waste.
 **Site contact signs for vaccine package**	Where over 80% of vials are intact and there are no concerns, the site contact will sign for the package.
 **Site contact stores vaccine in cold chain accredited conditions**	The site contact will then store the vaccine at cold chain conditions in the internal packaging carton it arrived in (not the Credo Cube, but the white vaccine box) until the use-by date and time marked on the vaccine box is reached. Any vials that are not viable must be disposed of following the disposal process detailed above.

10.5 Vaccine Storage & Handling

MoH is currently reviewing the processes for storing and delivering vaccine at -15 to -20°C following MedSafe's approval of this change. We will provide updates on changes to vaccine storage and handling once design and planning have been completed.

10.5.1 Cold chain storage

All facilities must hold cold chain accreditation as per the National Standards for Vaccine Storage and Transportation for Immunisation Providers (2017).

Vaccine must be stored and transported in cold chain accredited conditions. MoH requires that any individuals responsible for handling the vaccine have completed the appropriate cold chain training.

Further information on cold chain management is available in section 2.1 of the Immunisation Handbook. See also the manufacturer's specifications for approved product handling, available at: https://www.medsafe.govt.nz/profs/datasheet/c/comirnatyinj.pdf.

10.5.2 Handling refrigerator temperature excursions

The following advice applies to handling the Comirnaty™ vaccine (mRNA vaccine by Pfizer/BioNTech). In its thawed and undiluted state can be stored at room temperature (+8°C to +30°C) for up to 2 hours (120 minutes). This includes any breaches above +8°C that occur during storage in the vaccine refrigerator.

If your refrigeration fails and your data logger readings confirm your vaccine has been exposed temperature of +8°C to +30°C for more than 2 hours (120 minutes) or to temperatures below 0°C you need to:

- Label the vaccines 'not for use'.
    - If the refrigerator is currently running within the +2°C to +8°C range, leave the labelled vaccines in your refrigerator.
    - If the refrigerator is not within the +2°C to +8°C range, look for obvious reversible causes (door open, power interruption). If no cause found, pack your labelled vaccines into a chilly bin, with a temperature monitoring device and consider transporting to your back-up provider (details for this are in your cold chain policy).
- Contact your local immunisation coordinator for advice and further actions. Email is covered from 8:30am to 5pm weekdays or you can contact the Clinical Advice line (0800 IMMUNE) for guidance up to 8pm weekdays or on weekends.
    - Northern: Lisa Box lisa.box@auckland.ac.nz
    - Midland: Olivia Haslam Olivia.Haslam@auckland.ac.nz
    - Central: Melanie Miller Melanie.Miller@auckland.ac.nz
    - Southern: Sue Rogers Sue.Rogers@auckland.ac.nz
- Document the steps and actions you have taken.

10.5.3 Vaccine quantities and package sizes

Unit	Size
Full tray	290 x 290 x 40 mm
15 vial pack	130 x 130 x 45mm
5 vial pack	130 x 65 x 45mm

10.5.4 Shelf-life of vaccine

Size	-90°C to -60°C	At +2°C to+8°C	At ambient temperature (up to +30°C)
Frozen Tray or Vial	**6 months** from date of manufacture	**Note:** In preparing to transport, based on current stability studies, a tray of 195 vials may take up to 3 hours to thaw in the refrigerator. A smaller number of vials will thaw in less time. *	**Closed lid trays:** Up to **5 minutes** for transfer between ULT environments. **Open lid trays:** Up to **3 minutes** for transfer between ULT environments. **Note:** Following room temperature exposure, trays must be returned to the ULT -70°C freezer for 2 hours before they can be removed again.
Thawed Tray or Vial (undiluted)	N/A	**31days** from time of removal from ULT. **Note:** Transportation time at +2°C to +8°C is included in the **31**-day limit.	**2 hours**
Prepared Dose	N/A	**6 hours**	**6 hours**

*__Note:__ If you are transferring vials from -20°C to a +2°C to +8°C, you should expect vials to take approximately 30 minutes to thaw, provided they are spaced apart and not in a tray. In this scenario, vials would be spaced approximately 2.5cm apart in the +2°C to +8°C refrigerator.

Vaccine shelf-life is also visualised in the table below.

<table>
<tr><th>Ultra-Low Temperature (-90°C to -60°C)</th><th>Refrigerated Temperature (2°C to 8°C)</th><th>Room Temperature (8°C to 30°C)</th></tr>
<tr><td rowspan="4">6 months from date of manufacture</td><td colspan="2">Undiluted Vaccine</td></tr>
<tr><td>31 Days</td><td>2 hours before dilution
This includes time for thawing and/or to come to room temperature (may take up to 30 minutes)</td></tr>
<tr><td colspan="2">Diluted Vaccine</td></tr>
<tr><td colspan="2">Use within 6 hours
Any vaccine remaining in vials or syringes must be discarded after 6 hours</td></tr>
</table>

Please note that each of these "stages" are separate, so for undiluted vaccine, there is a 2-hour window where you can keep the vaccine at room temperature once removed from refrigerated temperature. Should you dilute the vaccine in 30 minutes, it does not provide an additional 1.5 hours of expiry to diluted vaccine in room temperature; once the vaccine is diluted, it only has a 6-hour expiry.

Vaccine in an ULT environment has an expiry of 6 months from the date of manufacture (this will be reflected as the expiry date on the vial and tray). Total time, if you were to only progress from each stage after the **maximum allotted time**, it will be as follows:

- Post-ULT → **31 days** in refrigerated temperature (not diluted) → 2 hours in room temperature (not diluted) → 6 hours in refrigerated or room temperature (diluted); that is **31 days** + 2 hours + 6 hours.

10.5.5 Movement of vaccine

Vaccine can be carefully moved around a vaccination facility, though you should minimize any unnecessary movement or handling. For example, carefully walking vaccine from one floor to another within a facility is okay; running with it in your pocket is not.

Do not shake the vaccine at any stage of transportation, preparation or administration. If vials are dropped or if you are concerned about whether the vaccine is still viable, please contact IMAC for advice on 0800 IMMUNE (466 863), option 1 (Health professionals) and then option 2 (COVID vaccinator support).

10.6 Repacking Vaccine at DHB Facilities

Only a DHB hospital pharmacy department can re-pack the vaccine packs received from the distribution provider. They can do this under their hospital pharmacy license and are only able to do this for supply within their DHB. In this circumstance, 'DHB' means within the DHB legal entity – e.g. can repack the vaccine packs down to smaller sized packs and distribute to a vaccinator or site that is DHB run/vaccinator DHB employee.

DHB hospital pharmacy departments are not able to re-pack the vaccine packs for supply to people outside of their DHB. If they are to be required to do this, the relevant DHB hospital pharmacy department will need a packing license issued to them by Medicines Control.

10.7 Transportation of Vaccine to Other Locations

Unused, undiluted vials of vaccine that are not needed, or approaching their expiry date and will not be used in the clinic before expiry, must be sent to the hospital pharmacy for redistribution. Send the vials in their original box. The cold chain must be maintained throughout the transportation process.

DHB vaccinators may go to an accepted alternate location to deliver vaccine. In this case, the vaccine must be transported and stored under cold chain conditions.

10.7.1 Transit time for thawed vials

Any hours used for transport of unopened vials at 2°C to 8°C count against the 31-day limit for storage at 2°C to 8°C.

10.7.2 Transportation of diluted or drawn-up vaccine

You may move a few pre-drawn syringes of vaccine within a facility for immediate use e.g. across the carpark to another vaccinating tent/marquee, or to another floor in the building/hospital for administration to a patient. The syringes must be appropriately labelled (content, volume, batch and expiry).

However, the bulk preparation of pre-drawn vaccine to be transported to another location is regarded as compounding and is not permitted unless it is undertaken in an approved facility (e.g., a hospital pharmacy aseptic unit or a third party commercial compounder) with appropriate checks, documentation and audit by the regulator. If you do undertake compounding, diluted vaccine can be in transit for up to 6 hours at 2°C to 30°C.

In all circumstances, any hours used for transportation counts against the 6-hour expiry limit for storage at 2°C to 30°C. Microbiological risks and package integrity, particularly for prepared dosing syringes, are the responsibility of the preparer during transportation of diluted vaccine.

10.8 Returning Credo Cubes and Temperature Monitoring Equipment

Vaccination sites or DHB/provider facilities must return the Credo Cube and temperature monitoring equipment in a timely manner – preferably on the same day as receipt - to ensure there are no interruptions of subsequent vaccine deliveries. Pre-paid stickers will be included with the delivery for returns. Please call the number on the instructions to arrange collection. Please report any fault or damage to the Credo Cube or equipment to the provider if needed at time of return.

You may need to remove/cross out the original courier label and original address details.

10.9 Inventory Reporting

The MoH Logistics team will continue to monitor demand and allocation using data from CIR and information from liaison with DHBs or providers. DHB and provider Logistics Leads must supply daily stocktake reporting on:

- Stock consumption and waste
- Stock on hand
- Stock transfers

The MoH Logistics team will liaise with Logistics Leads to collect this information through an agreed mechanism.

11. CIR Inventory Module

11.1 Purpose and Overview of Module

The COVID-19 Immunisation Register (CIR) module provides a centralised place to vaccine and consumables orders, manage stock on hand (SOH), arrange transfers, record consumption and wastage of unopened vaccine vials.

Inventory is the term used to describe how much product or stock (in this case vaccine and consumables) is at a location at any point in time. The inventory module is the place where the movement (transactions) and use of that stock is managed and recorded.

These records allow for the effective management of stock at each location, ensuring optimum use and minimise wastage of vaccines and consumables. There are several inventory management processes each location will need to perform:

- Stock on hand (Daily stock takes)
- Stock movements (including ordering, transfers, wastage, consumption, and stock adjustments)
- Quarantine of stock
- Repacking of stock

11.2 Logging in to CIR

You can request access to the CIR Location and Inventory portal by contacting the Ministry of Health help@C-19imms.min.health.nz or 0800 223 987.

To access to the live CIR Location and Inventory portal click here: https://ncts.force.com/cir/s/

If you cannot remember your password or you have trouble logging in, please contact help@C-19imms.min.health.nz or 0800 223 987.

Further detail about how to log into the CIR can be found in the quick guides, videos, detailed training guide on https://circlassrm-ncts.cs116.force.com/cir/s/article/CIR-Inventory-Orders-Portal-Quick-Step-Guide

11.3 Inventory Orders

Vaccine stock (inventory) can be ordered using the CIR in two ways:

1. Direct from the national distribution hubs using a 'Supplier Order', or
2. From another Vaccine site using a 'Transfer Order'. Both steps detailed in sections below.

The Standard Operating Procedures for order fulfilment have been inserted below as a PDF document.

SOP Order Fulfilment.pdf

11.3.1 Supplier Order

A Supplier Order is an order where the stock will come directly from a national distribution hub and the order must be approved by the Ministry of Health team.

Users must be associated with a Location to place a Supplier Order.

Further detail about how to log into the CIR can be found in the quick guides, videos, detailed training guide on https://circlassrm-ncts.cs116.force.com/cir/s/article/CIR-Inventory-Orders-Portal-Quick-Step-Guide

See the 'Inventory Orders' section for the Standard Operating Procedures for order fulfilment.

11.3.2 Cancelling Orders

Orders can be cancelled before they are approved by the Ministry of Health. This is to allow corrections to orders that might be incorrect or orders that are no longer required.

Further detail about how to log into the CIR can be found in the quick guides, videos, detailed training guide on https://circlassrm-ncts.cs116.force.com/cir/s/article/CIR-Inventory-Orders-Portal-Quick-Step-Guide

See the 'Inventory Orders' section for the Standard Operating Procedures for order fulfilment.

11.3.3 Receipting Orders

When a vaccine or consumables order is received, it needs to be 'receipted' into the system. The purpose of this is to move the stock from 'in transit' to 'available for use' in the stock on hand.

Further detail about how to log into the CIR can be found in the quick guides, videos, detailed training guide on https://circlassrm-ncts.cs116.force.com/cir/s/article/CIR-Inventory-Orders-Portal-Quick-Step-Guide

See the 'Inventory Orders' section for the Standard Operating Procedures for order fulfilment.

11.3.4 Transfer Orders

A Transfer Order is a transfer between two locations. It used routinely to transfer stock between DHB Hospital Pharmacies and mobile vaccination sites.

For fixed vaccination sites, the transfer order process is only used for surge/back-up transfers for delivery from DHB Hospital Pharmacies, or end of day returns between two locations.

Users must be associated with a Location to place a Transfer Order.

Further detail about how to log into the CIR can be found in the quick guides, videos, detailed training guide on https://circlassrm-ncts.cs116.force.com/cir/s/article/CIR-Inventory-Orders-Portal-Quick-Step-Guide

The Standard Operating Procedures for inventory management have been inserted below as a PDF document.

SOP Inventory Management.pdf

11.3.5 Recording Consumption

It is important to record the consumption of vaccine stock and consumables as stock in consumed or, at least, as part of the daily stocktake. The purpose of this is to give an accurate local, regional, and national view of vaccine stock on hand.

Consumption can be recorded in two ways:

1. Consumption – entering directly what has been consumed
2. Stock on hand – entering a physical count of the stock on hand as part of the daily stocktake.

Further detail about how to log into the CIR can be found in the quick guides, videos, detailed training guide on https://circlassrm-ncts.cs116.force.com/cir/s/article/CIR-Inventory-Orders-Portal-Quick-Step-Guide

See the 'Transfer Orders" section for the Standard Operating Procedures for inventory management.

11.3.6 Recording Vaccine Waste

It is important for vaccine sites to record vaccine waste in the CIR Logistics Portal, but only to the unopened vial level (the recording of vaccine wasted at the opened vial level is yet to be determined). This is so that waste can be tracked at a local, regional, or national level and.

Further detail about how to log into the CIR can be found in the quick guides, videos, detailed training guide on https://circlassrm-ncts.cs116.force.com/cir/s/article/CIR-Inventory-Orders-Portal-Quick-Step-Guide

See the 'Transfer Orders" section for the Standard Operating Procedures for inventory management.

11.4 Vaccine and Consumables Assets and Asset Management

An asset is an instance of vaccine stock and vaccine consumables e.g. 5 pack, 15 pack, 195 pack of vaccine, or consumable 'kit'.

Assets at a Location can be updated through:

- Stock Re-work
- Stock Adjustment
- Quarantine stock
- Recording Consumption, or
- Stock on Hand.

Further detail about how to log into the CIR can be found in the quick guides, videos, detailed training guide on https://circlassrm-ncts.cs116.force.com/cir/s/article/CIR-Inventory-Orders-Portal-Quick-Step-Guide

See the 'Transfer Orders" section for the Standard Operating Procedures for inventory management.

11.5 Reports

The COVID-19 Immunisation Register (CIR) portal provides a centralised place for operational reporting including demand forecast, inventory management including stock on hand, and orders approved for sites.

These operational reports can be generated for providers by the Ministry of Health CVIP Logistics Customer Services Team and will made available to providers in the future.

11.6 Support

The Ministry of Health provides two levels of customer support.

Level one is the Ministry's IT Helpdesk. The helpdesk deals with login and access issues. They can be contacted on help@C-19imms.min.health.nz or 0800 223 987.

Level two is the CVIP Logistics Customer Services team. They can assist with support for order placing and approval, inventory management, and use of the CIR Inventory Portal. Once the vaccination site has been onboarded, you will be given the contact details for this team.

12. National Immunisation Booking System

12.1 Introduction

The National Immunisation Booking System (NIBS) known as 'Book My Vaccine' is being rolled out across New Zealand throughout June and July of 2021 to support a national-led approach to immunising New Zealand against COVID-19. This system will replace the distinct booking solutions and methods currently used across the nation by each DHB. Book My Vaccine will support vaccination Sites down to the Community Hub, with primary care sites that are only serving their own enrolled population as optional in this first deployment.

This chapter details an operating guide for Book My Vaccine – the key stakeholders, staff roles, system, processes, and operating guides related to running the Book My Vaccine tool.

This chapter is to be used as the first point of reference for all Book My Vaccine related activities by any DHB staff members who will be responsible for running vaccine sites and managing bookings. A detailed guide that includes detailed process flows will be published soon. Training and user guides are also provided and can be accessed via the below links:

CIR All Training Material Link:

https://circlassrm-ncts.cs116.force.com/cir/s/recordlist/Knowledge__kav/00B5O000001CNbyUAG

Individual guides below:

NIBS:

https://circlassrm-ncts.cs116.force.com/cir/s/article/CIR-Bookings

https://circlassrm-ncts.cs116.force.com/cir/s/article/CIR-Bookings-Not-NHI-Matched-Quick-Step-Guide

Accenture Vaccine Management System (AVMS):

https://circlassrm-ncts.cs116.force.com/cir/s/article/NIBS-Site-Admin-Managing-Overrides-exceptions-Guide

https://circlassrm-ncts.cs116.force.com/cir/s/article/NIBS-Site-Admin-Managing-Capacity-Guide

For any information which is not included in these documents, the DHB is advised to communicate with MoH.

This guide will be amended as required and the latest version will be made available via:

https://circlassrm-ncts.cs116.force.com/cir/s/recordlist/Knowledge__kav/00B5O000001CNbyUAG

12.2 Booking System Principles

The creation and operating model of Book My Vaccine is based off the following four principles regarding responsibility and Governance between MoH, Whakarongorau Aotearoa (Whakarongorau) and DHBs. These guiding principles are intended to promote consumer safety, equity, and trust in the system. These are detailed in the next four steps:

1. Setup: The Book My Vaccine tool will support the nationally led and locally delivered vaccination programme

    - The Ministry of Health has overall coordination and monitoring responsibility including overall messaging leading nation-wide booking campaigns.

    - DHBs have responsibility for vaccinating their populations, including localising campaigns to meet vaccination targets.

2. Setup: The Book My Vaccine tool will be implemented by all DHBs

    - The Book My Vaccine tool will be the trusted source of available booking slots for the public, the DHBs and for Whakarongorau Call Centre to see what appointments are available for booking.

    - All vaccination site types down to Community Hub level will use the Book My Vaccine tool. General Practices and Pharmacies will initially have the option of either using their own system for vaccination scheduling or the Book My Vaccine tool.

3. Pre-event: The Book My Vaccine tool will be provided as a package with Whakarongorau as the National Call Centre

    - Whakarongorau will only support the Book My Vaccine tool and no other booking systems once the Book My Vaccine tool is operational. Legacy booking systems will be phased out or replaced.

    - Whakarongorau will provide a consumer supporting role for public queries (in-bound) and assisted booking for all DHBs and sites available on the Book My Vaccine tool.

4. Post-event: The management of following up individuals for missed vaccination appointments will be a mixed model

    - Whakarongorau can provide the service for follow-up of missed appointments (outbound calling) if agreed with the DHB, before passing on to DHB teams for intensive outreach follow-up. This agreement will be defined between the DHB and Whakarongorau in the engagement plan.

    - Otherwise: DHBs will follow up on missed appointments (outbound calling), or can be supported by local models with Primary Health Organisations or Iwi providers

12.3 Booking System Roles

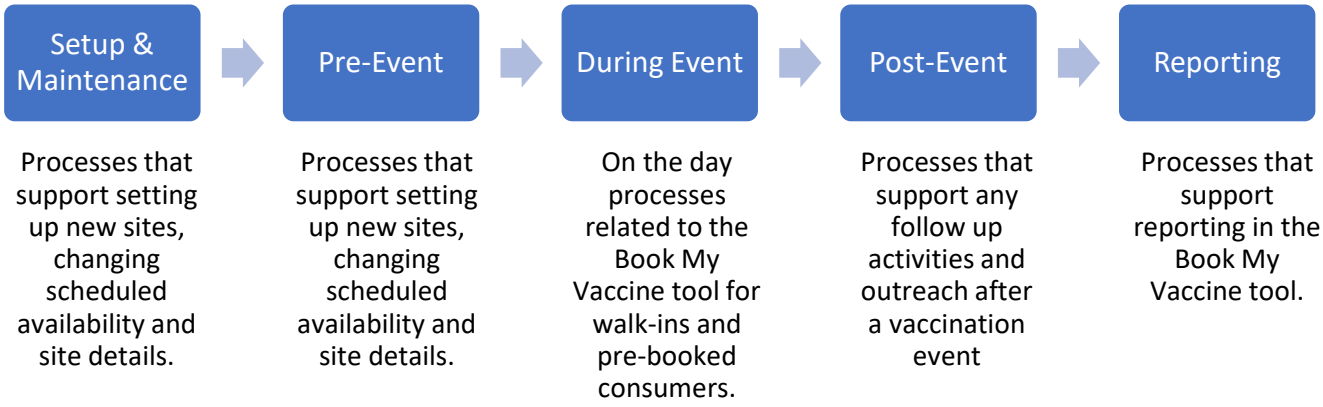
The following are key roles which have been identified to support the Book My Vaccine tool. These roles include staff from the vaccination site, DHB, MoH and Whakarongorau. Further information related to the expected support, behaviour and outcomes of these roles is detailed below in section 4.2.2.

Key Roles	Role Description
Site Receptionist	The Site Receptionist manages on-site check-in procedures and performs health checks prior to vaccination. The Site Receptionist is provisioned the role of Concierge in the Book My Vaccine tool.
Whakarongorau National Call Centre Coordinator	The Whakarongorau National Call Centre Coordinator is the inbound point of entry for all booking queries. They are responsible for assisting consumers with creating, cancelling, and amending bookings, completing follow up activities where commissioned to do so and answering general vaccine related queries. They are provisioned the role of Special Concierge in the Book My Vaccine tool.
Whakarongorau DHB Liaison	The Whakarongorau DHB Liaison is the primary point of contact for communications and escalations for booking related processes that require Whakarongorau interactions. They are responsible for the operation of the contact centre and for escalating issues with MoH Operations Leads and the DHB Operations Leads as required. The Whakarongorau DHB Liaison and details on how to contact them will be agreed as part of the engagement plan.
Site Lead	The Site Lead manages the day-to-day operation of their site and are the primary point of communication for the site. They are responsible for identifying and escalating any scheduling changes to the DHB Site Admin.
Site Admin	The Site Admin maintains the Site Admin Role in the booking system, and acts as the first point of escalation in managing the technical operations of the system for the sites they oversee (recommended to have 1 Site Admin per 10 sites). They are responsible for triaging and escalating (minor/major event) site schedule changes.
DHB Site Admin	The DHB Site Admin acts as the first point of escalation for managing the technical operations of the system for the sites they oversee (recommended 1 Site Lead per 10 sites). They are responsible for triaging and escalating impactful (Minor/Major event) site schedule changes. The DHB Site Admin is provisioned the role of Site Admin in the Book My Vaccine tool.
DHB Operations Lead	The DHB Operations Lead is accountable for managing the operational activities for a DHB. Their key roles include generating reports to identify DHB follow-up activities, managing all escalations that are required to be raised to a DHB's attention and sharing escalations with MoH and Whakarongorau as required. They are accountable for the accuracy of all site schedules.
MoH Operations Lead	The MoH Operations Lead is the primary point of contact for escalations into the Ministry of Health. Their key obligation is managing communications between MoH and Whakarongorau/DHBs. They are provisioned the role of Super User in the system, and are responsible for onboarding users, creating DHBs and initial Site creation in the system.

Figure 5: Key Role Descriptions

12.4 Booking System Processes & Best Practice

All booking tool processes have been categorised into the following five areas:



12.4.1 Setup & Maintenance

12.4.1.1 Create New Site

Creating a new site relates to setting up a greenfield site after the initial DHB deployment on the Booking system. Once the requirement for a new site has been identified, the DHB will define their invitations strategy and requirements, after which they can begin to define their engagement plan with the DHB Liaison. Whakarongorau would like seven days of lead time from this initial discussion before booking can be made on the new site.

The DHB will populate the New Site CIR and NIBS setup forms which DHBs filled out for the initial Go-live deployment. The DHB Operations Lead is then required to email the forms to the MoH Central Help Desk. The information within this form is used by teams within MoH to setup the new site in CIR and NIBS. It will take up to 72 hours for these sites to be created in the respective systems after form submission. In June and July, before the general population is invited to book their vaccine doses, access codes will also be created and sent in an email to the DHB Operations Lead alongside the Site creation details.

After this information has been received by MoH, the Adoption and Improvement (A&I) team will contact the DHB Operations Lead to commence user training for both NIBS and CICS (COVID Immunisation Consumer Support) (if the DHB is using CICS – use will be optional). System users will be trained for the Site Admin and Concierge roles in NIBS and the System user role for CICS. The A&I team will inform MoH once system user training has been completed (it is mandatory that training is completed before users are provisioned). MoH will then provision the appropriate users for the Site. The DHB Operations Lead will receive a confirmation of this task completion through an email.

The DHB and Whakarongorau DHB Liaison will agree an engagement plan for the new site. It is best practice that a QA approval process is then undertaken by MoH to ensure that the Site has been set up correctly. Upon approval, NIBS will be ready to take bookings.

12.4.1.2 Amend Site Schedule

Amending a site schedule involves updating the capacity and availability of appointment slots for a site. The Site Lead or Site Admin is responsible for identifying major schedule changes, escalating these with the DHB Operations Lead and making necessary changes in the system. The thresholds for escalation will be set and be maintained by each DHB.

It is important to note that changing the schedule in NIBS does not cancel or reschedule any existing bookings. Refer to Section 4.3.1.3 Event Rebooking for details.

It is crucial that the Site Lead/Admin performs an impact assessment regarding bookings when amending a site schedule, specifically when the number of appointment slots are reduced.

12.4.1.3 Event Rebooking

In the case that an event causes a disruption to a site, where an existing schedule is set, and appointments are cancelled, consumers must be rebooked in the system. Event severity (minor or major – to be determined by the site and DHB staff), will dictate the applicable escalation path to ensure that key stakeholders have visibility of the event, and can assist with implementing appropriate resolution measures. The DHB Operations Lead should notify and work with their Whakarongorau DHB Liaison to build and execute an action plan to reschedule consumers. When a major event occurs, it is important to notify MoH of both the event and rescheduling action plan so that MoH can assist with the event and record the event for reporting purposes. In both cases, MoH needs to be informed.

It is important to note that rescheduling is not automatic. Consumers appointments will not be cancelled or rescheduled automatically when a site schedule change is created. Therefore, it is important to work with your DHB contact centre or with Whakarongorau to assist with outbound calling to rebook consumer appointments in a rebooking event.

12.4.1.4 Amend Site Details

Amending site details involves updating the site location and other site properties. These changes will not affect scheduling. The Site Lead, Site Admin or DHB Operations Lead is responsible for identifying that such changes are necessary. The Site Admin is responsible for making changes in the system. MoH should be notified of the change if it impacts the location of a site, so that Google Maps can be informed of the change.

12.4.2 Pre-Event

12.4.2.1 Booking an Appointment

If a consumer is eligible to be vaccinated or has an access code, they will be able to either book two appointments in the Book My Vaccine tool, or one appointment if they have already received their first vaccine dose (if the booking date is within 100 days of their first appointment). They will be asked to provide their personal details, allowing the system to send a booking reference and confirmation to the consumer. Bookings can also be made by an individual on behalf of a consumer (for instance a family member or friend), or through Whakarongorau. If a consumer is not eligible, they can register for updates on the website or end the assisted booking process.

12.4.2.2 Update/Cancel an Appointment

Consumers can update the time and/or location of their vaccine appointment(s) or cancel the appointment(s) through the Book My Vaccine tool. To do this they must access the link in the confirmation message they received when they made the original booking. If a consumer does not have this link, they should contact Whakarongorau for assistance. If there is less than two hours until the start time of an appointment, or the appointment start time has already passed, the option to rebook will be removed, and shown as grey on the tool.

12.4.3 During Vaccination Event

12.4.3.1 Consumer Arrival

If a consumer arrives at a site without an appointment (walk-in), the DHB can accommodate them (has capability to take walk-in consumers, and the site has availability, they must be booked into the Book My Vaccine tool for both their first and second appointment prior to vaccine administration. This ensures that consumers receive a second vaccine dose. The Book My Vaccine tool dictates that both first and second dose appointments must be booked into the same Site. For example, if a consumer is booked into one Site for their

first dose appointment, they must be also booked into the same Site for their second dose appointment. If the site does not have capacity to book in a consumer for a vaccination, the Concierge should assist the consumer in booking (a) future appointment(s).

12.4.4 Post Event: Follow-up

12.4.4.1 Booking Did Not Show (DNS) Follow-up

It will be defined in the engagement plan between Whakarongorau and each DHB which party is responsible for following up consumers through outbound calls. This will be a mixed model, where each party may be responsible for following up with different groups of consumers within the DHB. When a consumer does not show to their appointment, they will be contacted on three separate occasions. The best practice for following up is to contact a consumer the day after the missed appointment, followed by two more attempts at the fourth day and seventh day after the appointment if no contact attempt is successful. Should the consumer remain uncontactable, the DHB is responsible for executing the most suitable follow-up response (further outbound calls or ceasing follow-up communications).

Appendix A: Site Checklist

The following list provides an overview of the minimum requirements that you need to consider and have in place to safely and efficiently deliver COVID-19 vaccinations.

As a general principle, the site and staff should be prepared and adhere to standard operating policies and standards, including clinical governance and health and safety, that are expected in a clinical environment to ensure staff and consumer safety.

Physical site	**Yes / No**	**Comments**
Adequate space and associated capacity for registration, vaccination (including drawing up and administering) and post vaccination observation area		
Appropriate cold chain provisions that are applicable for the site, including having: • An appropriate individual to receive the vaccine • Appropriate refrigerators and opaque containers to store material		
Equipment that is not provided in the consumable pack, including: • kidney dish • PPE		
Appropriate signage to identify as vaccination site for consumers and associated consumer collateral including: • Getting your COVID-19 Vaccine: What to Expect • Consent form • After Your Immunisation • Vaccination receipt and second appointment card • Privacy statement • COVID-19 vaccination campaign posters/banners/flags • Hard-copy form to collect household contacts		
Facilities and processes in place to safely dispose of unused, damaged or empty vaccine vials (e.g. Interwaste vial disposal bin ordered)		
Appropriate protocols in place to safely manage waste		
Ability to maintain the room temperatures between 19-30°C		
Appropriate security provision to ensure vaccinator and consumer safety that is applicable and appropriate to the site context.		
Completed site risk assessment		
Appropriate emergency medication and equipment and protocol to respond to three possible medical emergencies associated with the vaccination (fainting, hyperventilation and anaphylaxis), as per IMAC guidelines and standard vaccination site protocol		
Information Technology	**Yes / No**	**Comments**
Sufficient tablets, laptops or desktop to access and operate CIR and complete inventory reporting requirements		
High speed wireless or 4G coverage		
Hard-copy consent forms with CIR data fields on the reverse and associated secure storage in case of system disruption		
Booking mechanism to support scheduling (A national solution is being developed)		

Screen to display IMAC video (if applicable)		
Workforce	**Yes / No**	**Comments**
Staffing levels are appropriate for delivering the scheduled vaccination volume. At a minimum the following functions need to be allocated: • Consumer welcome • Preparation and administration of doses, including obtaining informed consent (these could be separate roles) • Event recording in CIR by a CIR-trained person • After-immunisation observation		
Staff have completed relevant training and accreditations, including cold chain and vaccine accreditation and training, adverse event accreditation and training, and CIR training.		
All staff on site are appropriately briefed on the site protocol including the Operational Guidelines and are clear on their respective roles and responsibilities for the shift		
Vaccination event	**Yes / No**	**Comments**
Procedures for identifying vaccine recipients		
Standardised screening process for contraindications, receipt of previous dose of COVID-19 vaccine or other vaccines, and COVID-19 symptoms		
Ability to monitor, manage and report adverse events following immunisation, including anaphylaxis		
Incident management procedures are in place and staff know how to report any clinical incident		
Other considerations		
If you are working in MIQ or other location that may require additional infection prevention controls, please adhere to the standard SOPs and associated protocols, including physical distancing requirements		
If there is change in Alert Level, please adhere to the relevant PPE SOPs and associated protocol required to operate under the Alert Level, including physical distancing requirements		
If you are operating a drive-in facility, please have an appropriate Traffic Management plan in place		

Appendix B: New Facility/ Site Setup Form v1.3

New Facility / Site Set Up Form

This information must be provided to MoH five (5) days in advance of any initial deliveries. Please use the following template to complete the information required to enable us to set up a Vaccination Facility or Vaccination Site.

Please take care and provide detail when filling out the fields below as accurate information is required to ensure successful delivery of vaccines and consumables. *Return the completed form to your Regional Area Manager and CC: covid-19.logistics@health.govt.nz*

Has the site been signed off by the DHB CE?	☐ Please tick if yes	Please attach copy of signed authorisation

	Location Details		
A	**SITE**	***Only complete Section A if a site is being set up.*** ***Note: Sites are where vaccines are administered***	
SITE	**DHB**		Please provide the DHB in which the vaccination facility/site is located.
SITE	**Site Name**		Please provide the site name.
SITE	**Site Address**		Please provide the delivery address. Please include floor number/building number/gate number if relevant.
SITE	**Suburb and Post Code**		Please confirm the suburb and post code of this site.
SITE	**City**		Please confirm the city in which this site is located.
SITE	**Is this vaccination site also a facility?**		Yes/No.
SITE	**Site Type**		Select from: DHB | GP | Hospital | Marae or Cultural Hub | Mobile | Permanent Vaccination Centre | Pharmacy | Private Practice | Residential Facilities | Specialist | Workplace | Other
SITE	**Site Equity Focus**		Select from: Not applicable | Māori | Pacific Island | Disability | Mixed
SITE	**The following information relates to the Provider(s) responsible for the site.**		
SITE	**Provider Name**		Please provide the name of the primary provider
SITE	**Provider Type** (if Other please provide details)		Select from: DHB | Occupational Health | Community Pharmacy | GP | PHO | Kaupapa Maori | Pacifica Peoples' Provider | Private | Other
SITE	**Provider Equity Focus**		Select from: Not applicable | Maori | Pacific Island | Disability | Mixed
SITE	**Collaborating Provider Name**		Please provide the name of the collaborating provider (if applicable)
SITE	**Provider Type** (if Other please provide details)		Select from: DHB | Occupational Health | Community Pharmacy | GP | PHO | Kaupapa Maori | Pacifica Peoples' Provider | Private | Other
SITE	**Provider Equity Focus**		Select from: Not applicable | Maori | Pacific Island | Disability | Mixed
B	**FACILITY**	***Please provide Facility or Associated Facility details*** ***Note: Facilities are where vaccines are shipped, stored and distributed to sites.***	
FACILITY	**DHB**		Please provide the DHB where the facility is located.
FACILITY	**Facility Name**		Please provide the facility name if different to site name in Section A.
FACILITY	**Facility Type**		Please provide the facility type e.g. hospital, pharmacy, clinic.
FACILITY	**Facility Address**		Please include suburb, city and postcode
FACILITY	**Delivery Address** (if different from Facility Address)		Please advise the delivery address - include floor number/building number/gate number if relevant.
FACILITY	**Facility ID (HPI ID)**		What is this facility's ID (if unknown, state 'unknown')

Delivery Information														
Available delivery times (Mon-Sun)	Mon		Tue		Wed		Thu		Fri		Sat		Sun		Please provide us with the available delivery times for the facility for each day of the week e.g. 7am – 5pm Monday – Sunday.
	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	
Delivery Notes															Please add any comments which may assist the delivery driver in successfully completing deliveries to this facility.

New Facility / Site Set Up Form

Storage & Capacity			
Which of the following storage accreditations does facility provide?			
	Yes / No	**If yes, please provide details of how many vials can be stored**	
Ultra Cold (-70C)			
Frozen (-20C)			
Cold Chain (2-8C)			
Ambient			
Consumable Storage			Can consumables be stored at this location?
Data Logger Reader			Is there a data logger reader at this location? If yes, please provide details about brand/type.

Contact Information			
Named Role			Please confirm the "named role" at this vaccination facility/site who will be available and is authorised to receive the vaccine/consumables upon delivery e.g. Lead Nurse, Clinic Manager.
Name and Contact Phone Number of Named Role	**Name:**		Please confirm the name and contact phone number of the named role.
	Phone:		
Alternative Name and Contact Phone Number of other team members who fit the Named Role.	**Alternate 1**	**Name:**	Please confirm the names and contact phone numbers for all other team members that fit the 'named role'.
		Phone:	
	Alternate 2	**Name:**	
		Phone:	

Completed/Signed by:	**Name**		**Signature**	
	Title			

Appendix C: Document Version Control

Revision History

Version	Date	Section/ Appendix	Summary of Changes
0.1	14/2/2021		Draft version for input issued to DHBs to support Group 1 planning & operations
0.2	14/2/2021		Minor grammatical updates
1.0	18/2/2021		Significant changes including: • Addition of abbreviations table • Additional equity guidance • Additional clinical leadership guidance • Removal of 'Social distancing and consumer flow' section with detailed IPC section and guidance • Additional vaccine and on-site security guidance • Clarification of collateral available and purpose of each • Modified CIR access request process • Clarification of written consent process for Group 1 cohort • Guidance for situations when consumers are not in CIR or do not have a NHI number • Addition of waste disposal process, vaccine quality control process and clarification of Credo Cube return process • Additional detail on operational reporting that DHBs can request • Guidance on recording vaccine errors • Guidance on administering leftover vaccine
2.0	25/2/2021		Minor updates throughout to include providers as well as DHBs. Minor formatting changes throughout.
		1	Addition of link to Immunisation Handbook as resource for clinical guidance on immunisations.
		5.4	Addition of new process for ordering Interwaste vial disposal bin; Interwaste contact details added to Key Contacts table.
		5.15.1	Updated section on running a site dry run
		5.13.3	Addition of CIR support process image
		7.2	Reformatting information on channels to collect household contacts in a table; additional channel added for collection during current DHB interactions with Border/MIQ staff.
		8.3 & 8.4	Existing content reformatted as tables with graphics; conducting clinical assessment and obtaining consent moved to vaccination process (from pre-vaccination process).
		8.4.1	Additional guidance on responding to adverse events on site.
		8.5	Updated text on recording vaccine errors
		8.7 & 8.8	Removal of requirement to monitor and report numbers of vials discarded to MoH.

		8.7.2 & 9.4	Added photo of Interwaste container and Credo Cube
3.0	4/3/2021	3 & 8.5	Updated phone number for IMAC clinical support
		5.1	Additional bullet points to encourage planning for consumers with visual or hearing impairments and support people who attend vaccination sites with consumers.
		5.7	Updated to include timeframe for entering hard-copy forms in CIR.
		8.1.1	Updated to clarify distinction between bulk-loading immunisation event records vs consumers for those on the BWTR; removed what was 8.3.1 as it duplicated information 8.1.1.
		8.3.1	Added note that collecting consumer residency information is not mandatory when setting up new NHI numbers.
		8.4.3	New content regarding COVID-19 treatment injury claims with ACC
		9.6.2	New guidance on managing refrigerator temperature excursions
4.0	11/3/2021	5.13	Note about consumers notifying their doctors that they've received the vaccine removed as completed vaccination records will now be passed to the Practice Management System (PMS).
		8.4	Post-vaccination observation period updated to 20 minutes from 30 minutes
		8.5	Updated guidance on reporting medical errors in CIR instead of on manual forms
		8.7.4	Updated guidance to note that vaccine vial boxes can be securely destroyed in document destruction bins or biohazard bags.
		9.6.4	Additional information on vaccine shelf-life timeframes.
5.0	25/3/2021	3.0	Updated phone number for obtaining clinical support from IMAC
		5.15	Additional information about obtaining CE (or their delegate's) approval of the site checklist to reflect current practice and submitting site details using the 'COVID-19 Vaccine Facility and Site Set Up Details' form
		8.2	Note to highlight that updated instructions on preparing and administering the Pfizer vaccine are available on 29 March
		9.4.1	New wording to note a local procedure should be in place to identify the individual(s) who may be transporting the vaccine
		9.5	Updated to note site contact and delivery details are submitted using the 'COVID-19 Vaccine Facility and Site Set Up Details' form.
		9.7	Clarification of wording regarding DHB hospital pharmacy repacking
6.0	1/4/2021	5.15.1	Removed reference to ordering a Credo Cube for site dry-run
		8.1.2	New information to clarify timeframe for scheduling consumers for their second dose
		8.2	Guidance to note vaccine should not be cold to the touch at time of dilution
		8.4	• Updated clinical assessment wording

			• Removal of note stating written consent must be obtained for Group 1 consumers to avoid confusion; currently, written consent must be obtained for all consumers.
		8.4.1	New sub-section to outline expectation to have appropriate processes in place to provide enhanced care to individuals with a history of adverse events following immunisation
		8.7.1	Minor wording update to clarify that DHBs/providers are responsible for arranging for disposal of consumables and other medical waste
		9.2	Updated to reflect timeframes and processes for site and facility set-up, demand planning, and ordering vaccine and consumables
		9.4	Additional guidance about interpreting the temperature logger lights
7.0	8/4/2021	8.4	Additional point to note expiry date on vial should be recorded in CIR
		8.6.1	Updated guidance about transporting leftover vaccine (thawed or diluted) to other sites if needed.
		9.5	Wording to note MoH is currently exploring vaccine storage and handling at -15 to -25°C
		9.5.5	New guidance about moving vaccine on site
		9.7.1 & 9.7.2	New guidance about transporting vaccine (thawed or diluted) and transit times
8.0	15/4/2021		Revisions throughout to prepare this document for public release
		5.18	New section on site access and traffic management considerations
		5.4	New section on quality and safety oversight
		6.1	New content to suggest site staff are offered vaccination prior to commencing operations
		6.4	Updated links to IMAC resources
		8.4.1 & 8.4.1.1	New section on obtaining informed consent, including new guidance about when to obtain written or verbal consent. Section on uploading consent forms to CIR moved to this section.
		9.2.3 & 9.2.3.1	Updated wording around ordering and the process for urgent orders
		9.5.2	Updated wording on managing temperature excursions and IMAC regional coordinator contact details
		9.7.1	Removal of 12-hour transit time reference
9.0	22/4/2021	6.4	New section on setting up mobile vaccination teams
		8.2.1	New guidance on the number of doses per vial
		8.3.2	Interim advice on dealing with individuals who have received their first dose of the Pfizer vaccine overseas
		8.4.1 & 8.4.1.2	Clarification on which consent forms to use for Tier 1 and when consent forms may be varied

		8.4.2	• Additional note to highlight the importance of using the correct length needle when administering the vaccine • Additional note to emphasise the importance of giving the vaccination receipt card as proof of vaccination
		8.6	Slight wording update to 8.6 and removed 8.6.1
		9	Removed caveat that guidance only relates to Tier 1
		9.5.4	Added note about thawing times from ULT to shelf-life table
		9.7	Updated guidance on returning undiluted vials to the hospital pharmacy for redistribution
		9.8	Updated wording about reporting damage or faults with Credo Cube or temperature monitoring equipment
10.0	6/5/2021	3 & 5.16	Updated CARM reporting link to the COVID-specific CARM form
		8.3.1	Updated instructions on creating new NHI numbers and linking them in CIR; you no longer need to wait 24 hours for NHI numbers to pass to CIR.
		8.3.2	Clarification on administering Pfizer vaccine if consumer has received the first dose of a different two-dose vaccine overseas.
		8.4.1	Updated wording to reflect that the Group 1a consent form has been withdrawn
		8.4.2	New section on recording information in CIR
		8.8 & 9.2.2	Updated wording to note that daily inventory reporting and demand forecasts can now be submitted through the CIR inventory portal
		9.2.3	New diagram to show vaccine ordering process
		9.2.4	Correction to consumables table to list 25-gauge needles instead of 21-gauge
11.0	13/5/2021	8.1.2	Clarification to wording around the interval between first and second doses.
		8.3.1	Additional information about what to advise the MoH contact centre if you contact them to request a new NHI number
		8.3.2	Updated to reflect new CIR functionality to record doses administered both in NZ and overseas
		9.5.5	Clarification on contacting IMAC if vials are dropped
12.0	20/5/2021	8.4.2	Updated wording to note that CIR records must be created at the time of vaccination
		8.4.3	New note to clarify the distinction between cancelling and rescheduling event records in CIR
		9.2.4 & 9.2.5	New instructions for ordering consumable kits with vaccine orders
		9.5.4	New note to on thawing time for vials moved from -20°C to +2°C to +8°C
		9.7.2	Updated guidance on transporting diluted vaccine

13.0	3/6/2021	5.1.1, 5.1.2 & 5.1.3	New sub-headings under Equitable Access (5.1) for more clarity
		5.1.2. 6.2	Additional information around access for disabled people
		5.5.3.1	Additional information on injection safety
		5.12.1	Added subsection about sharing information on the vaccine on site
		5.15.1	Updated process on how to complete CIR and IMAC training
		5.17	Wording to reflect that primary care providers may submit site checklists to DHBs rather than to MoH directly
		6.3	Changed "Nurse" to "Registered Health Professional" Added new notes to provide clarity when utilising COVID-19 vaccinators
		6.5	Noted that eLearning module for health professionals with prescriber rights is available
		8.2	Added note to follow IPC policies
		8.4.1	Additional information on informed consent
		8.4.4	Added recommendation to use simulation scenarios to prepare staff to respond to adverse events
		9.2.4	Changed consumables 'kits' to 'packs'; updated quantity for 10ml saline in Pack 2; updated package dimensions for Pack 2
		9, 9.3.3 & 9.5.4	Updated the expiry time of the vaccine (while being stored at 2°C to 8°C) from 120 hours to 31 days
		9.5.1	Updated information regarding cold chain storage accreditation for all facilities
14.0	17/06/2021	3	Changed "If an individual has an adverse event" to "Reporting an adverse event"
		4	Removed mask purchasing from DHBs & Providers and added PPE purchasing to Ministry of health
		5.5	Removed information on mask wearing during vaccination. However, additional IPC precautions may be necessary in the context of the COVID-19 pandemic (e.g. PPE usage in line with the current Alert Level)
		5.17	Updated the form name to "New Facility/ Site Set Up Form (v13.0)"
		6.2	Changed "recovery room" to "observation area"
		6.3	Table 1 "After the Event" column • Removed information about contacting household members. • Changed "Registered/Practice Nurse" to "Registered Health Professional". • Changed "support person with bystander CPR/ first aid training" to "support person with CPR training" Table 2 • Removed "imms event" for clarity
		8.1.2	Changed "at" to "from" clarifying that the booking of the second dose appointments can be made at any time given the appointment is 21 days after the first dose Removed information to call IMAC when booking second dose appointments
		8.2	Additional information around foreign bodies and discolouration of the vaccine and information about labelling vials after vaccine dilution
		8.2.1	Added note when drawing up less than 6 doses
		9.2.3	Changed delivery of vaccines from daily to weekly
		9.2.4	Changed "request consumables" to "order consumables"
		9.2.6	Updated information on PPE ordering for current and new providers
		9.4	Updated information on step "Site contact conducts visual check" around broken vials and waste
		9.9	Updated stock take information from weekly to daily Additional information to report stock consumption and waste

		10	New section covering CIR Inventory Portal